UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF TEXAS
AUSTIN DIVISION

LEAH SMITH AND STEVEN SMITH	§	**CASE NO.: 1:22-CV-871**
	§	
Plaintiffs,	§	
	§	
	§	
vs.	§	**ORIGINAL COMPLAINT FOR**
	§	**DAMAGES AND JURY DEMAND**
	§	
COLOPLAST CORP., COLOPLAST MANUFACTURING US, LLC., and BOSTON SCIENTIFIC CORP.	§	
	§	
	§	
Defendants.	§	

Plaintiffs Leah Smith and Steven Smith ("Plaintiffs") file this Original Complaint for causes of action against Defendants Coloplast Corp., Coloplast Manufacturing US. LLC. and Boston Scientific Corp. and allege as follows:

INTRODUCTION

Plaintiffs, by undersigned counsel, bring this Complaint against Coloplast Corp., Coloplast Manufacturing US, LLC., and Boston Scientific Corp. (collectively referred to herein as "Defendants") related to the design, manufacture, marketing, distribution, and sale of Defendants' Pelvic Mesh Products implanted in Plaintiff Leah Smith. This action is for compensatory, equitable, injunctive, and declaratory relief. Plaintiffs make the following allegations based upon their individual personal knowledge as to their own acts, and upon information and belief, as well as upon her attorneys' investigative efforts as to Defendants' actions and misconduct and alleges as follows.

PARTIES AND SERVICE

1. Plaintiffs Leah Smith and Steven Smith are residents and citizens of Leander, Williamson County, Texas. Plaintiff has suffered and continues to suffer significant injury as a result of Defendants' products and the conduct alleged herein.

2. Defendant Coloplast Corp. ("Coloplast Corp.") is a corporation organized and existing under the laws of the State of Delaware, maintaining its principal place of business at 1601 West River Road North, Minneapolis, Minnesota 55411. Coloplast Corp. is a wholly- owned U.S. sales and marketing subsidiary of Coloplast A/S, a Denmark corporation. Its registered agent office in Texas is Corporation Services Company, 211 E. 7th Street, Suite 620, Austin, Texas 78701.

3. Defendant Coloplast Manufacturing US, LLC is a limited liability corporation organized and existing under Delaware law maintaining its principal place of business at 1940 Commerce Drive, North Mankato, MN, 56002. Its registered office is 560 Park Street, #6, St. Paul, Minnesota 55103. Coloplast Manufacturing US, LLC is a wholly-owned subsidiary of Coloplast Corp.

4. Coloplast Corp. and Coloplast Manufacturing US, LLC, are collectively referred to herein as "Coloplast."

5. Defendant Boston Scientific Corporation ("Boston Scientific" or "BSC") is a corporation organized and existing under the laws of the State of Delaware and maintains its principal place of business at One Boston Scientific Place, Natick, Massachusetts 01760. Its registered agent office in Texas is Corporation Services Company, 211 E. 7th Street, Suite 620, Austin, Texas 78701.

6. All acts and omissions of the above-referenced Defendants as described herein were done by its agents, servants, employees, and/or owners, acting in the course and scope of their respective agencies, services, employments, and/or ownership.

JURISDICTION AND VENUE

3. This Court has jurisdiction over this action by virtue of 28 U.S.C. § 1332, in that the amount in controversy exceeds Seventy-Five Thousand Dollars ($75,000.00) exclusive of interest and costs and because there is a complete diversity of citizenship between Plaintiffs and Defendants.

4. Venue is proper in this Court pursuant to 28 U.S.C. § 1391(a) by virtue of the fact that Defendants are doing business in this judicial district, subjecting Defendants to personal jurisdiction in this action and making it a "resident" of this judicial district.

5. Plaintiff was implanted with vaginal mesh products designed, manufactured, distributed, and sold in interstate commerce, including in Travis County, Texas (implant location) and Williamson County, Texas (Plaintiffs' County of residence).

6. At all relevant times, Defendants expected or should have expected their acts would have consequences within the United States of America and in the Western District of Texas, in particular.

FACTUAL BACKGROUND
Transvaginal Mesh (TVM) Products

A. General Factual Allegations

7. At all times material to this lawsuit, Coloplast Corp, Coloplast Manufacturing US, LLC, and Coloplast A/S designed, manufactured, labeled, marketed, and sold a line of mesh products for the treatment of Pelvic Organ Prolapse (POP). This line of products includes the

Coloplast Restorelle XL 30x30cm for POP that was vaginally implanted into Plaintiff Leah Smith by Dr. Shashoua on December 16, 2016.

8. At all times material to this lawsuit, Coloplast Corp, Coloplast Manufacturing US, LLC, and Coloplast A/S designed, manufactured, labeled, marketed, and sold a line of mesh products for the treatment of Pelvic Organ Prolapse (POP). This line of products includes the Coloplast Direct Fix Anterior for POP that was vaginally implanted into Plaintiff Leah Smith by Dr. Shashoua on October 1, 2018.

9. At all times material to this lawsuit, Boston Scientific Corporation designed, manufactured, labeled, marketed, and sold a line of mesh products for the treatment of Stress Urinary Incontinence (SUI). This line of products includes the Boston Scientific Advantage Fit implanted into Plaintiff Leah Smith by Dr. Shashoua on December 16, 2016.

10. The term "Products" used hereinafter means Coloplast Restorelle XL and Boston Scientific Restorelle XL implanted into Plaintiff Leah Smith on December 16, 2016, and the Coloplast Direct Fix Anterior implanted into Leah Smith on October 1, 2018.

11. A pelvic organ prolapse occurs when a pelvic organ, such as the bladder, drops (prolapses) from its normal position and pushes against the walls of the vagina. Prolapse can happen if the muscles that hold the pelvic organs in place become weak or stretched from childbirth or surgery. More than one pelvic organ can prolapse at the same time. Organs that can be involved in a pelvic organ prolapse include the bladder, the uterus, the bowel, and the rectum.

12. Stress urinary incontinence is a type of incontinence characterized by leakage of urine during moments of physical stress.

13. This is an action to recover damages for personal injuries suffered by Plaintiff Leah Smith as a result of the implant of the Restorelle XL, Direct Fix Anterior, and Advantage Fit

products, as tested, studied, researched, evaluated, endorsed, designed, formulated, compounded, manufactured, produced, assembled, inspected, distributed, marketed, labeled, promoted, packaged, advertised for sale, prescribed, sold or otherwise placed in the stream of interstate commerce by Defendants and implanted by Dr. Shashoua and Defendant Austin Urogynecology.

14. At all times herein mentioned the officers and directors of Coloplast participated in, authorized, and directed the production and promotion of Restorelle XL and Direct Fix Anterior when they knew, or with the exercise of reasonable care should have known, of the hazards and dangerous propensities of the devices and thereby actively participated in the tortious conduct which resulted in the injuries suffered by Plaintiff Smith.

15. At all times herein mentioned the officers and directors of Defendant Boston Scientific participated in, authorized, and directed the production and promotion of the Advantage Fit device when they knew, or with the exercise of reasonable care should have known, of the hazards and dangerous propensities of the Advantage Fit and thereby actively participated in the tortious conduct which resulted in the injuries suffered by Plaintiff Smith.

16. The Products at issue here are made from polypropylene. This material is incompatible with human tissue found in the pelvis / vagina and promotes a negative immune response in a large subset of patients.

17. When Boston Scientific's Advantage Fit and Coloplast's Restorelle XL and Direct Fix Anterior are inserted in the female body according to the manufacturers' instructions, they create a non-anatomic condition in the pelvis leading to chronic pain and functional disabilities.

18. Despite claims that polypropylene mesh is inert, scientific evidence shows that this material, after implanted is biologically incompatible with human tissue and when used as a woven or knitted alloplastic textile prosthetic mesh for pelvic floor repair, polypropylene and other

surgical polymers promote a severe foreign body reaction and chronic inflammatory response in a large subset of the population implanted with Defendants' Pelvic Mesh Products. This "host defense response" by a woman's pelvic tissues promotes degradation of the polypropylene mesh and the pelvic tissue, and causes chronic inflammation of the pelvic tissue, shrinkage or contraction of the mesh leading to nerve entrapment, further inflammation, chronic infectious response and chronic pain. It also can cause new-onset painful sexual relations, significant urinary dysfunction, vaginal shortening, vaginal anatomic deformation, and can contribute to the formation of severe adverse reactions to the mesh.

19. Surgical mesh, including mesh used Pelvic Mesh Products implanted into Plaintiff Leah Smith, is a medical device that is generally used to repair weakened or damaged tissue. It is made from absorbable or non-absorbable synthetic material or absorbable biologic material. In urogynecologic procedures, surgical mesh is permanently implanted to reinforce the weakened vaginal wall to repair pelvic organ prolapse or to support the urethra to treat urinary incontinence.

20. The mesh implanted into Plaintiff Leah Smith is a knitted polypropylene mesh with small pores. Both products implanted into Plaintiff Leah Smith, have small pores due to the pores collapsing when implanted and in vivo due to the normal loads and forces applied to the mesh, as well as unintended shrinkage/contracture, scar plating and deformation. Numerous scholarly articles and research have concluded polypropylene mesh with small pores is dangerous and increases the frequency, severity and duration of injuries from transvaginal mesh devices. Specifically, the small pore polypropylene mesh causes complex erosions and extrusions in women that persistently recur, chronic pelvic and vaginal pain, inability to engage in intercourse and complex painful revision surgeries to cut and tug mesh pieces from the vagina.

21. At all times material to this action, Defendants designed, patented, manufactured, packaged, labeled, marketed, sold, and distributed a line of pelvic mesh products, intended to treat pelvic organ prolapse and/or urinary incontinence, including the Coloplast Restorelle family of products and Boston Scientific Advantage Fit. Each of these products was cleared for sale in the United States after the Defendants made assertions to the Food and Drug Administration of "Substantial Equivalence" under Section 510(k) of the Food, Drug and Cosmetic Act; this clearance process does not require the applicant to prove safety or efficacy.

- Coloplast Restorelle XL Mesh and Direct Fix Anterior

22. Coloplast's Restorelle line of products was originally designed by Mpathy Medical Devices. Mpathy Medical Devices sought 510(k) FDA approval of the Restorelle line of products, not the Coloplast entities. On October 29, 2010, Coloplast Corp. acquired Mpathy Medical Devices, Inc. ("Mpathy"). Coloplast acquired Mpathy's core product lines including Minitape® and Omnisure® for stress urinary incontinence, and the Restorelle® family for pelvic organ prolapse. The Coloplast entities performed due diligence on Mpathy's Restorelle line of products prior to purchase and had actual knowledge that clinical evidence and medical literature showed the Restorelle line of products were defective.

23. Coloplast's Restorelle Polypropylene Mesh received 510K approval to market by the FDA on Dec. 22, 2010. Prior to Dec. 22, 2010, Restorelle Polypropylene Mesh was submitted to the FDA for 510K approval by Mpathy Medical. All Restorelle pelvic mesh products utilize Coloplast's "Smartmesh" polypropylene. Coloplast claims, among other things, that the "Smartmesh" used in Restorelle is the lightest mesh available in women's health, has uniform 1.8 mm macropores, allows for vaginal elasticity to be maintained, has 100-micron interstitial pores, low memory, and multi-dimensional stretch.

24. Coloplast's Restorelle XL and Direct Fix Anterior utilize the Restorelle mesh.

25. Coloplast promoted the Restorelle XL implanted into Plaintiff Leah Smith, as safe, effective, reliable, minimally invasive, and superior to alternative treatments for POP.

26. Coloplast promoted their products through sales representatives. The role of the sales representative was to push the benefits of the products while minimizing the risks and hold their products out as superior to competitors' products. Additionally, sales representatives conveyed critical information to implanting physicians regarding implant selection, patient selection, implant technique, and post-surgical treatment.

27. Coloplast knew that Dr. Shashoua was implanting the Restorelle XL "off label" by implanting the Restorelle XL transvaginally to correct Leah Smith's prolapse. Despite this, Coloplast continued to promote the product to Dr. Shashoua to be implanted "off label."

28. Implanting Restorelle XL and Direct Fix Anterior transvaginally for pelvic organ prolapse creates risks that far outweigh any benefits, with unacceptable rates of mesh exposure, erosions, dyspareunia, chronic or permanent pelvic pain, painful mesh shrinkage, nerve damage, revisions, and re-operations in attempts to address these complications, and reoccurrences of prolapse following mesh removal surgeries. Transvaginal implantation of Restorelle XL and Direct Fix Anterior products does not result in superior functional outcomes for patients as compared to traditional non-mesh surgeries. When the definition of a successful prolapse repair surgery includes consideration of both anatomic and functional outcomes, it is clear that the risks of transvaginal placement of Restorelle and Direct Fix Anterior far outweigh the potential benefits. Defendant Coloplast knew that these risks outweighed the benefits to Plaintiff Leah Smith prior to the products being implanted.

29. No clinical studies of Restorelle transvaginal mesh products studying the product inside the female pelvis occurred prior to it being marketed.

30. The Restorelle XL and Direct Fix Anterior implanted into Plaintiff Smith was to correct pelvic organ prolapse.

31. From December 22, 2010, to August 2, 2013, Restorelle XL was indicated for use for the repair of abdominal wall hernia, including inguinal, femoral, and incisional, and uterovaginal prolapse and other fascial deficiencies that require support material. During this period, Restorelle XL was indicated to be implanted via open or laparoscopic abdominal procedures or for repair by the vaginal route.

32. In the wake of the FDA's 522 Orders on transvaginal mesh products, like the Restorelle XL, Coloplast **changed** the indications for use of Restorelle XL and removed the indication that Restorelle XL could be implanted through the vagina. On August 2, 2013, the FDA cleared this narrowed indication for Restorelle XL and removed the allowance for implantation through the vagina from Restorelle XL's label.

- Boston Scientific Advantage Fit

33. Boston Scientific manufactures and markets transvaginal mesh—a medical device designed to be permanently implanted into women's bodies. Advantage mesh, which BSC uses for all its transvaginal mesh, is subject to regulation by the U.S. Food and Drug Administration ("FDA"), as well as other regulations and laws. BSC's Advantage mesh was made from Marlex HGX-030-01, a specific and unique polypropylene, which was cleared by the FDA under its 510(k) approval process.

34. BSC's Advantage Mesh, Advantage Fit, and Lynx Systems were cleared for sale by the FDA through its 510(k) process on or about April 2, 2002. To gain clearance under the

FDA's 510(k) process, a manufacturer must prove that the product it attempts to put on the market is substantially equivalent to predicate devices cleared by the FDA. BSC specified that the mesh would be made from Marlex HGX-030-01 and that its predicate devices were Tension Free Vaginal Tape ("TVT"), BioSling, Mentor Suspend Sling, and BSC's Trelex Mesh.

35. At all relevant times, Marlex HGX-030-01 was manufactured and trademarked by a joint venture between Chevron and Phillips/Sumika (Phillips) in LaPorte, Texas. Marlex is sold in its raw form as pellets. By law, BSC is required to manufacture Advantage mesh from Marlex HGX-030-01. If BSC used anything other than Marlex HGX-030-01 to form its mesh, the product would not be Advantage mesh, as approved by the FDA. In short, Phillips Marlex comprises BSC's Advantage mesh, which in turn comprises BSC's transvaginal mesh products. If BSC cannot get Marlex, then it cannot make its transvaginal mesh that was cleared by the FDA.

36. While also being made of polypropylene, the mesh used in the BSC Advantage Fit has different properties than the mesh used in Coloplast's Restorelle product line, namely the Advantage Fit mesh has smaller pores, higher density, and heavier weight than the Restorelle device.

37. Boston Scientific promoted the Advantage Fit implanted into Plaintiff Leah Smith, as safe, effective, reliable, minimally invasive, superior to alternative treatments for SUI, and properly cleared by the FDA.

38. Boston Scientific promoted their products through sales representatives. The role of the sales representative was to push the benefits of the products while minimizing the risks and hold their products out as superior to competitors' products. Additionally, sales representatives conveyed critical information to implanting physicians regarding implant selection, patient selection, implant technique, and post-surgical treatment.

- **Boston Scientific purchased counterfeit Marlex from China for use in mesh products.**

39. To gain FDA clearance, BSC represented to the FDA it used a specific plastic resin (Marlex HGX-030-01) to make Advantage mesh - the backbone of the BSC Stress Urinary Incontinence (SUI) product group (Advantage, Obtryx, Lynx and Solyx and all its transvaginal mesh products). The FDA allowed BSC's mesh products based on that representation. Authentic Marlex resin was manufactured by a joint venture of Chevron and Phillips. Marlex is a trademarked, specific brand and is identified in the industry as Marlex HGX-030-01.

40. Marlex HGX-030-01 resin is a polypropylene plastic that comes in the form of pellets. For several years, Phillips has issued revised Material Safety Data Sheets ("MSDS") for Marlex polypropylene. BSC was aware of the Marlex MSDS at all relevant times, including when it manufactured and marketed its mesh products to Plaintiff and Class Members. The MSDS contains the following warning:

> "MEDICAL APPLICATION CAUTION: DO NOT USE THIS CHEVRON PHILLIPS CHEMICAL MATERIAL IN MEDICAL APPLICATIONS INVOLVING PERMANENT IMPLANTATION IN THE HUMAN BODY OR PERMANENT CONTACT WITH INTERNAL BODY FLUIDS OR TISSUES.
>
> DO NOT USE THIS CHEVRON PHILLIPS CHEMICAL COMPANY LP MATERIAL IN MEDICAL APPLICATIONS INVOLVING BRIEF OR TEMPORARY IMPLANTATION IN THE HUMAN BODY OR CONTACT WITH INTERNAL BODY FLUIDS OR TISSUES UNLESS THE MATERIAL HAS BEEN PROVIDED DIRECTLY FROM CHEVRON PHILLIPS CHEMICAL COMPANY LP UNDER AN AGREEMENT WHICH EXPRESSLY ACKNOWLEDGES THE CONTEMPLATED USE.
>
> CHEVRON PHILLIPS CHEMICAL COMPANY LP MAKES NO REPRESENTATION, PROMISE, EXPRESS WARRANTY OR IMPLIED WARRANTY CONCERNING THE SUITABILITY OF THIS MATERIAL FOR USE IN IMPLANTATION IN THE HUMAN BODY OR IN CONTACT WITH INTERNAL BODY FLUIDS OR TISSUES."

41. On information and belief, in 2005, Phillips terminated its contract with BSC for Marlex HGX-030-01 because the product was not intended for use in permanent implant devices.

In 2005, Phillips only allowed BSC to buy an additional 4,000 pounds of Marlex HGX-030-01. After that, Phillips cut off BSC from getting any more authentic Phillips Marlex from Phillips to permanently implant into women.

42. On information and belief, in 2011, BSC's supply of Marlex resin began to run precariously low. BSC projected it would run out of Marlex August/September 2012. If BSC wanted to maintain the $120,000,000 in annual mesh sales, it would need to find more Phillips Marlex resin. In July 2011 BSC requested that Phillips sell them one million pounds of the Marlex resin. On July 27, 2011, Phillips refused to sell Marlex to BSC.

43. China has a well-known dark history of supplying counterfeit, adulterated products. More specifically, China is known to produce counterfeit mesh. The medical device maker Bard was forced to recall thousands of its mesh products because its distributor used a counterfeit Marlex. On information and belief, BSC considered five potential Chinese sellers of Marlex, all found on alibaba.com. Ultimately, BSC settled on EMAI to purchase additional polypropylene from so that Boston Scientific mesh products could continue to be made. EMAI's headquarters sit squarely within the Guandong province of China—an area of rampant counterfeiting with highly publicized arrests and prosecutions doing little to slow down the counterfeiting machine it has become.

44. On information and belief, divisions within Boston Scientific knew that EMAI had attempted to sell counterfeit resin to Boston Scientific previously. Another division within BSC warned all divisions, including BSC's Women's Health Division, that EMAI had attempted to sell counterfeit polypropylene resin to them, despite this information the Women's Health Division completed its purchase of counterfeit Marlex resin from EMAI to use in their vaginal mesh products.

45. On information and belief, EMAI claimed its product was Phillips Marlex HGX-030-01; however, EMAI lacked the necessary paperwork to prove the authenticity of the supposed Marlex resin. EMAI could not show BSC that the Marlex was ever imported into China. Worse, EMAI could never show BSC a Certificate of Compliance or Certificate of Analysis that, by BSC's own standards, is necessary to accept a product from abroad.

46. If the EMAI resin were authentic and legally imported to China from Phillips, upon arrival in China, the Chinese importers would have required a "Certificate of Compliance" (C of C) or Certificate of Analysis (C of A) to ensure authenticity and country of origin. This would ensure that Chinese customs collected the proper import taxes. This certificate details important authenticity information such as the name, the manufacturer, the purchaser, the lot number, product property(ies), test method, value, and unit, purchase order, and packaging information.

47. When goods are brought into China, an import tax must be paid and documentation obtained that proves the goods cleared customs. If those goods are ever exported out of China, import documentation and tax receipts must be produced to Chinese officials to prove that the goods cleared customs upon import and that taxes were paid. If the goods have been modified in China, the Chinese government then charges a value added tax to the increased value of the good when exported and requires the same import documentation and tax receipts in order to calculate the value added tax. Without this documentation, one cannot legally export from China a good that was originally manufactured outside of China. EMAI has never produce the proper import and tax documentation identifying the Marlex resin coming into China or leaving China.

48. On information and belief, Boston Scientific attempted to verify with Phillips whether the polypropylene resin sought to be purchased from EMAI was in fact Marlex HGX-030-01. However, Phillips confirmed that the product from EMAI was not Marlex HGX-030-01.

49. On information and belief, despite having clear knowledge that the product being offered for sell by EMAI was not authentic Marlex HGX-030-010, Boston Scientific went through with the purchase of the product and purchased a total of 37,400 pounds of the product from EMAI. It is believed that BSC intended that this EMAI resin would last for 25 years, meaning, BSC could continue to implant counterfeit mesh into unsuspecting women through the year 2032.

50. On information and belief, since Boston Scientific could not locate the Certificates of Compliance or Certificates of Analysis, the EMAI resin was required to be smuggled out of China by various measures in order to get the resin to locations to be manufactured into mesh products.

51. On information and belief, Boston Scientific performed limited test on the Chinese resin. However, the test results showed in the Chinese mesh as compared to true Marlex. For example, the results show:

a. **Weaker fibers with molecular variations.** The test results showed different molecular strings, different string lengths and a wider variation in the bell curve, indicating a different and/or substandard manufacturing process;
b. **Different Catalysts**. Sample 2 used a different catalyst (titanium) than samples 1 and 3.
c. **Control sample fails the test**. Sample 3, which was supposed to be the control, did not even pass the melt rate standard for Marlex;
d. **High levels of selenium.** Selenium is a rare, toxic element. Selenium reacts with hydrogen peroxide to form selenic acid, a strong oxidant, which attacks polypropylene, resulting in the rapid degradation of the mesh implanted in Plaintiff.

52. On information and belief, testing performed by Boston Scientific revealed that the mesh used to create the Advantage Fit sling implanted into Leah Smith was not true Marlex and exposed Leah Smith to additional injuries.

- **FDA Action Pertaining to Transvaginal Mesh Products**

53. On October 20, 2008, the U.S. Food and Drug Administration (FDA) issued a Public Health Notification that described over a thousand (1,000) complaints (otherwise known as "adverse events") that had been reported over a three-year period relating to the Pelvic Mesh Products and other similar products.

54. Unbeknownst to the Plaintiffs, the FDA issued an updated safety alert on July 13, 2011, wherein the FDA stated that "serious complications associated with surgical mesh…are **not rare**" (emphasis in the original). The FDA had also received increased reports of complications associated with the transvaginal mesh in both pelvic organ prolapse and stress urinary incontinence cases.

55. The FDA Safety Communication also stated, "*Mesh contraction* (shrinkage) is a *previously unidentified risk* of transvaginal…repair with mesh that has been reported in the published scientific literature and in adverse event reports to the FDA. Reports in the literature associate mesh contraction with vaginal shortening, vaginal tightening and vaginal pain." (emphasis in original).

56. The FDA Safety Communication further indicated that the benefits of using Pelvic Mesh Products instead of other feasible alternatives did not outweigh the associated risks. Specifically, the FDA Safety Communication stated: "it is not clear that transvaginal POP repair with mesh is more effective than traditional non-mesh repair in all patients with POP and it may expose patients to greater risks."

57. In December 2011, the FDA released a publication titled "Urogynecologic Surgical Mesh: Update on the Safety and Effectiveness of Transvaginal Placement for Pelvic Organ Prolapse" (the White Paper). In the White Paper, the FDA noted that the published, peer-reviewed

literature demonstrates that "[p]atients who undergo…repair with mesh are subject to mesh-related complications that are not experienced by patients who undergo traditional surgery without mesh." The FDA summarized its findings from its review of the adverse event reports and applicable literature stating that it "has NOT seen conclusive evidence that using transvaginally placed mesh…improves clinical outcomes any more than…repair that does not use mesh, and it may expose patients to greater risk." (emphasis in original).

58. In a December 2011 Joint Committee Opinion, the American College of Obstetricians and Gynecologists ("ACOG") and the American Urogynecologic Society ("AUGS") also identified physical and mechanical changes to the transvaginal mesh inside the body as a serious complication associated with transvaginal mesh, stating:

> There are increasing reports of vaginal pain associated with changes that can occur with mesh (contraction, retraction, or shrinkage) that result in taut sections of mesh . . . Some of these women will require surgical intervention to correct the condition, and some of the pain appears to be intractable.

59. In September 2011, the FDA acknowledged the need for additional data and noted in "Surgical Mesh For Treatment of Women with Pelvic Organ Prolapse and Stress Urinary Incontinence" that the literature and information developing on SUI repair with Pelvic Mesh Products "indicate that serious complications can occur . . . [and] a case can be made for additional premarket and/or post market studies to better address the risk/benefit of all mesh products used for SUI."

60. In December 2011, ACOG published a position paper which stated, "[t]here are insufficient data on the use of mesh for the posterior or apical compartments."

61. In January 2012, the FDA ordered manufacturers of urogynecologic surgical mesh devices to conduct post-market surveillance studies ("522 studies") to address specific safety and effectiveness concerns related to surgical mesh used for transvaginal repair of POP. This order was

based on the FDA's evaluation of the published literature, analysis of adverse events reported to the FDA, and feedback from the 2011 Panel meeting. In total, the FDA issued 131 post-market study orders to manufacturers of surgical mesh for transvaginal repair of SUI and POP. Coloplast's Restorelle XL and Direct Fix Anterior mesh received 522 Orders from the FDA for post-market surveillance studies. The FDA ordered the Coloplast to perform post-market studies evaluate the safety and effectiveness of these mesh devices when used to treat SUI and POP and determine if the benefit/risk profile of each device supports continued marketing of the devices.

62. On November 16, 2012, due to the 522 orders, Coloplast discontinued marketing of Restorelle EZA, EZP, P and L products. Each of these products contained the same mesh as the Restorelle XL product implanted into Plaintiff Leah Smith.

63. After the FDA issued 522 Orders on Restorelle Devices implanted via the transvaginal route, Coloplast sought to narrow the Restorelle XL Indication for Use and remove its indication for repair by the vaginal route. On August 2, 2013, Coloplast received notice from the FDA that Coloplast's 510(k) application to change the transvaginal indication for Restorelle XL to transabdominal/sacrocolpopexy (SCP) indication only was accepted. Therefore, any use of Restorelle XL transvaginally for the correction of pelvic organ prolapse is considered off-label use beginning on August 2, 2013.

64. In January of 2016, the FDA completed its reclassification of surgical mesh for transvaginal repair of POP into the highest risk class of devices (class III) and required premarket approval applications to be filed for products to stay on the market.

65. On February 12, 2019, the FDA held an advisory committee meeting to share the available evidence and seek expert opinion on how to evaluate the risks and benefits of these devices. The committee was asked to provide scientific and clinical input on assessing the

effectiveness, safety, and benefit-risk of mesh placed transvaginally in the anterior vaginal compartment, as well as identifying the appropriate patient population and physician training needed for these devices.

- **Defendant Coloplast and Defendant Boston Scientific's Marketing and Clinical Studies of Vaginal Mesh Devices**

66. The Defendants made the decision to use and market a low elasticity or stiff polypropylene mesh in the Restorelle XL, Direct Fix Anterior, and Advantage Fit mesh medical devices. Upon information and belief, Coloplast has touted the stiffness of its pelvic mesh products as having "low elasticity." Numerous scholarly articles and research have concluded stiff polypropylene mesh is not compatible with soft vaginal tissue, is dangerous and increases the frequency, severity and duration of injuries from transvaginal mesh devices. Specifically, the stiff polypropylene mesh causes complex erosions and extrusions in women that persistently recur, chronic pelvic and vaginal pain, inability to engage in intercourse and complex painful revision surgeries to cut and tug mesh pieces from the vagina

67. The Defendants made the decision to use and market the devices implanted into Plaintiff Smith, resulting in mesh that contracts, curls, coils, migrates and erodes through vaginal tissue after it is introduced into soft vaginal tissue. Numerous scholarly articles and research have concluded stiff polypropylene mesh with small pores is not compatible with soft vaginal tissue, is dangerous and increases the frequency, severity and duration of injuries from transvaginal mesh devices because the mesh does not hold in place after it is introduced into the body. Specifically, the polypropylene mesh contracts, moves around, migrates, deforms, curls, coils, folds over and causes complex erosions and extrusions in women that persistently recur, chronic pelvic and vaginal pain, inability to engage in intercourse and complex painful revision surgeries to cut and tug mesh pieces from the women's vaginas.

68. The Defendants chose to design and market the Restorelle XL, Direct Fix Anterior, and Advantage Fit to appeal to its customers, choosing to market their products and surgical approaches as "simplified," "easy and fast," "easy to implant," and "designed specifically with a woman's anatomy and tissue healing in mind." Decreasing the surgery time is an important marketing tool used by Defendant Coloplast to sell the device to surgeons.

69. The Coloplast Defendants specifically marketed Restorelle XL and Restorelle Direct Fix Anterior as being specifically designed for female anatomy, however has no data, testing, or information to substantiate these claims.

70. Defendants Coloplast and Boston Scientific knew that while the design features of the Restorelle XL, Direct Fix Anterior, and Advantage Fit could aid in the marketing of the device, it was in exchange for the serious, life-long, irreversible injuries to patients that would be caused by its design.

71. The scientific evidence shows that this stiff polypropylene mesh with small pores as implanted in the Plaintiff is biologically incompatible with vaginal tissue and when used as a woven or knitted prosthetic mesh in the vagina promotes a severe foreign body reaction and chronic inflammatory response in women implanted with the mesh device. This "host defense response" by a woman's pelvic tissues promotes deformation, curling, coiling and stiffening of the mesh, mesh migration, contraction and shrinkage of the mesh, excessive scarring and scar plating around the mesh, and degradation of the polypropylene mesh and the pelvic tissue, and causes chronic inflammation of the pelvic tissue and tissue damage, chronic infectious response and chronic pelvic and vaginal pain. It also can cause new-onset painful sexual relations, significant urinary dysfunction, vaginal shortening and anatomic deformation, and can contribute to the formation of severe adverse reactions to the mesh.

72. Defendant Coloplast and Defendant Boston Scientific did not adequately study the extent of the risks associated with the Restorelle XL, Direct Fix Anterior, and Advantage Fit intended to be permanently implanted in a woman's body. On information and belief, these Defendants did not make any effort or spend any time, money or resources to conduct long-term randomized controlled trials with safety as the primary end-point to study the frequency, severity and duration of adverse events associated with the Products.

73. Defendant Coloplast and Defendant Boston Scientific knew or should have known that the Restorelle XL, Direct Fix Anterior, and the Advantage Fit unreasonably exposed patients to the risk of serious harm while conferring no benefit over available feasible alternatives that do not involve the same risks. At the time the Defendants began marketing the Products, and at the time Plaintiff was implanted with the Products, Defendant Coloplast, the Defendants were aware that these products were associated with life-long irreversible adverse events, were unreasonably dangerous, and increased the frequency, severity and duration of adverse events due to their unsafe design features described herein.

74. On information and belief, neither Defendant Coloplast nor Defendant Boston Scientific made any effort or spent any time, money or resources in educating physicians, or patients, in how, if at all possible, to safely remove the Restorelle XL, Direct Fix Anterior, and Advantage Fit from a woman's body if complications occur.

75. Defendant Coloplast and Defendant Boston Scientific misled doctors and patients as to the performance, efficacy and safety of the Restorelle XL, Direct Fix Anterior, and Advantage Fit devices.

76. Defendant Coloplast misrepresented in its marketing statements that its pelvic organ prolapse devices, such as the Restorelle XL and Direct Fix Anterior, had "low complications

and high success." Defendant Coloplast touted their pelvic organ prolapse mesh as "physiologically compatible," "non-palpable," possessing a "high safety profile" and fighting bacteria, that it was "inserted through a small incision" and "held in place by narrow portions of the mesh." Defendant Coloplast further misrepresented that the placement of their devices "is not considered to be a major procedure" and results in "low incidence[s] of de novo dyspareunia" and that after placement, the mesh "maintain[s] vaginal elasticity of natural tissue" among others.

77. Defendant Coloplast and Defendant Boston Scientific never warned that complete removal of the Restorelle XL, Direct Fix Anterior, and Advantage Fit implanted into Plaintiff Smith may be impossible should complications occur.

78. Defendant Coloplast was aware that large surface-area polypropylene vaginal mesh grafts, like Restorelle XL and Direct Fix Anterior, are associated with greater bacterial contamination, more polypropylene degradation, increased inflammatory response, fibrous tissue stimulation, and erosion.

79. Defendant Coloplast and Defendant Boston Scientific intended patients and doctors to rely on these statements in choosing the Restorelle XL, Direct Fix Anterior, and Advantage Fit devices.

80. Defendant Coloplast and Defendant Boston Scientific knew or should have known the statements were false and/or inaccurate about the Products implanted into Plaintiff Leah Smith.

81. Defendant Coloplast and Defendant Boston Scientific omitted, misrepresented and/or downplayed the risks, dangers, defects, and disadvantages of the Restorelle XL, Direct Fix Anterior, and Advantage Fit, and advertised, promoted, marketed, sold and distributed the Products as safe medical devices with high success and low complications. However Defendant Coloplast and Defendant Boston Scientific knew or should have known that the Products were not safe for

their intended purpose, and that the Products would cause, and did cause, serious medical problems, and in patients, including Plaintiff Leah. Smith, catastrophic injuries.

82. Defendant Coloplast and Defendant Boston Scientific collected adverse event data related to patients Dr. Shashoua's implanted Defendants' devices into. Defendant Coloplast and Defendant Boston Scientific failed to inform Dr. Shashoua of adverse events experienced by Dr. Shashoua's own patient population that were known to the mesh manufacturing company.

83. The magnitude and frequency the problems associated to Restorelle XL, Direct Fix Anterior, and Advantage Fit were not disclosed and were hidden from Plaintiff Leah Smith by Defendant Coloplast and Defendant Boston Scientistic.

84. Contrary to Defendant Coloplast and Defendant Boston Scientific's representations and marketing to the medical community and to the patients themselves, the mesh used in the Restorelle XL, Direct Fix Anterior, and in Advantage Fit has high rates of failure, injury, and complications, fails to perform as intended, requires frequent and often debilitating re-operations, and has caused severe and irreversible injuries, conditions, and damage to a significant number of women, including Plaintiff Smith, making the products defective under the law.

85. Upon information and belief, the Defendants have paid millions of dollars to individual consultant surgeons to adopt the device in their practice to induce other healthcare providers in purchasing their products. These "seeding trials" are a form of marketing conducted in the name of research by Defendant Coloplast, specifically designed to target product sampling towards selected consumers.

86. Upon information and belief, Defendant Shashoua and Defendant Austin Urogynecology have maintained a financial relationship for more than 20 years with Defendant Coloplast and took part in these seeding trials for Defendant Coloplast.

87. On June 10, 2012, Dr. Shashoua and Coloplast Corp. entered into an automatically renewing Consulting Agreement that remains in place today. Coloplast Corp. has maintained regular contact with Dr. Shashoua via email, phone calls, text messages, and in-person meetings since prior to entering into the Consulting Agreement up to present day.

88. Coloplast Corp. has direct knowledge of Dr. Shashoua's use of Restorelle XL through the vagina to repair rectocele. In November of 2011 Coloplast and Dr. Shashoua collaborated on a video-recording project that recorded the very same procedure performed on Leah Smith 8 years later. Dr. Shashoua and Coloplast used this recording to promote the use of Coloplast's products. Defendant Coloplast also used Dr. Shashoua to teach his procedure that implants Restorelle XL through the vagina to correct rectocele to other doctors.

89. Upon information and belief, Defendant Coloplast and Defendant Boston Scientific have paid millions of dollars to consultant surgeons to have access and control over data that would be published on the safety of the devices used by their consultant surgeons.

90. Both Defendant Coloplast and Defendant Boston Scientific have made direct payments to Dr. George Shashoua or Austin Urogynecology.

91. In addition to the defects listed herein, the design of Restorelle XL, Direct Fix Anterior, and the Advantage Fit cause adverse tissue reactions and tissue death with a chronic inflammatory response, the mesh becomes more rigid and stiff and hardens with the presence of mesh in the this area of the body, and the mesh is inserted into and through an area of the body that is blood vessel rich, nerve dense, and bacteria laden leading to permanent nerve injury and associated chronic, intractable neuropathic pain, contaminated permanently-implanted mesh causing chronic infections, subclinical infections and biofilms, enhanced chronic inflammatory response, chronic wound healing with tissue destruction, as well as numerous other adverse

reactions and serious and permanent injuries that surgeons are unable to effectively completely alleviate due to the adherence of the mesh and scar-plating around the vaginal mesh.

92. The Restorelle XL, Direct Fix Anterior, and Advantage Fit products are also defective due to Defendant Coloplast and Boston Scientific's failure to adequately warn or instruct Plaintiff Smith and/or her health care providers, while at the same time misrepresenting the safety and performance features of the products.

93. Defendant Coloplast and Defendant Boston Scientific have underreported information about the propensity of the Restorelle XL, Direct Fix Anterior, and Advantage Fit to fail and cause injury and complications and have made unfounded representations regarding the efficacy and safety of the Products through various means and media.

94. Defendant Coloplast and Defendant Boston Scientific failed to perform proper and adequate testing and research in order to determine and evaluate the nature, magnitude and frequency of the risks attendant to the Products.

95. Defendant Coloplast and Defendant Boston Scientific failed to design and establish a safe, effective procedure for removal of the Product, or to determine if a safe, effective procedure for removal of the Products exists.

96. Feasible, suitable and safer alternatives to the Products implanted into Plaintiff Smith have existed at all times relevant that do not present the same severity of risks as do the Products.

97. The Products were at all times utilized and implanted in a manner foreseeable to Defendant Coloplast and Defendant Boston Scientific, as the Defendants respectively generated the instructions for use, created the procedure for implanting the device, distributed instructional

videos and materials, trained the implanting physicians, and endorsed Defendant Shashoua's technique of implantation.

98. As a result of these life-altering and, in some cases, permanent injuries, Plaintiff Smith has suffered severe emotional pain and injury and has suffered and will suffer apprehension of increased risk for injuries, infections, pain, mental anguish, discharge, and multiple corrective surgeries as a result of implantation of mesh.

99. The Products implanted in Plaintiff Smith were in the same or substantially similar condition as they were when they left the Defendants' possession, and in the condition directed by and expected by Defendants.

100. In many cases, including Plaintiff Leah Smith's, women have been forced to undergo extensive medical treatment including, but not limited to, multiple operations to locate and remove mesh, operations to attempt to repair pelvic organs, tissue, and nerve damage, the use of pain control and other medications, injections into various areas of the pelvis, spine, and the vagina, and operations to remove portions of the female genitalia.

101. Removal of segments of the contracted, curled, coiled, eroded, stiffened, small pore, scar-plated and/or infected transvaginal mesh can require multiple surgical interventions and result in further scarring on fragile compromised pelvic tissue and muscles.

102. At all relevant times herein, Defendant Coloplast and Defendant Boston Scientific failed to provide sufficient warnings and instructions that would have put Plaintiff and the general public on notice of the dangers and adverse effects caused by implantation of the Restorelle XL, Direct Fix Anterior and Advantage Fit products.

103. The Restorelle XL, Direct Fix Anterior, and Advantage Fit as designed, manufactured, distributed, sold and/or supplied by Defendant Coloplast and Defendant Boston

Scientific were defective as marketed due to inadequate warnings, instructions, labeling and/or inadequate testing in the presence of Defendants' knowledge of lack of safety.

104. The Defendants, through their product literature and sales representatives, omitted the risks, dangers, defects, and disadvantages of its products, and advertised, promoted, marketed, sold, and distributed the products as safe medical devices when they knew or should have known they were not safe for their intended purposes and that they could medical problems at rates higher than the rate disclosed to the medical community.

105. Medical literature shows that the Products at issue here are unreasonably susceptible to degradation and fragmentation inside the body; shrinkage or contraction inside the body; intense foreign body reaction; chronic inflammatory response; chronic wound healing; chronic infections in and around the mesh fibers; nerve entrapment in the collagen scar formation.

106. The Products at issue here have high rates of failure, injury, and complications, fail to perform as intended, require frequent and often debilitating re-operations, and have caused severe and irreversible injuries, conditions, and damage to a significant number of women, including Plaintiff Leah Smith, making them defective under the law.

107. The Products implanted into Plaintiff Leah Smith are defective and their defects include, but are not limited to, the following:

a. The use of polypropylene in the Products and the adverse tissue reactions and host defense response that result from such material, causing adverse reactions and serious, permanent injuries including, but not limited to, painful recurrent erosions and associated intractable pain;

b. The design of the Products to be inserted into and through an area of the body that is blood vessel rich, nerve dense, and bacteria laden leading to excessive blood loss and vascular damage, permanent nerve injury and associated chronic, intractable neuropathic pain, contaminated permanently-implanted mesh causing chronic infections, subclinical infections and biofilms, enhanced chronic inflammatory response, chronic wound healing with tissue destruction, as well as numerous other adverse reactions and serious and permanent injuries;

c. Biomechanical issues with the design of the Products which result in a nonanatomic condition leading to contraction or shrinkage of the mesh inside the body, that in turn causes surrounding tissue to become eroded, inflamed, fibrotic and infected, resulting in serious and permanent injury;

d. The propensity of the mesh design characteristics of the Products for plastic deformation when subjected to tension both during implantation and once implanted inside the body which causes the mesh, or portions thereof, to be encapsulated in a rigid scar plate which leads to nerve entrapment, bacterial entrapment, tissue destruction, enhanced inflammatory and fibrotic response and chronic pain;

e. The propensity of the Products to become rigid and inflexible, causing them to be improperly mated to the delicate and sensitive areas of the vagina and pelvis where they are implanted, and causing discomfort and pain with normal daily activities that involve movement in the pelvic region (e.g., intercourse, defecation, walking);

f. The propensity of the Products for degradation or fragmentation over time, which causes an increased surface area that leads to enhanced chronic inflammatory and fibrotic reaction, causes a "barbed wire" or "saw blade" affect by the fragmented surface "sawing" through the tissue, leads to bacteria harboring in the fragmented, peeled and split fiber surface which in turn leads to chronic infections at the mesh surface, and results in continuing injury over time;

g. The hyper-inflammatory responses to collagen leading to problems including chronic inflammatory response, chronic pain and fibrotic reaction as well as infections and other serious adverse events;

h. The propensity of the collagen products to disintegrate after implantation in the female pelvis, causing pain and other adverse reactions;

i. The harshness of collagen upon the female pelvic tissue, and the hardening of the product in the body; and

j. The inability of surgeons to effectively treat many of these conditions due to the integration of the mesh into the pelvic tissue and thus the inability to safely remove or excise the mesh once a complication occurs;

Leah Smith's Transvaginal Mesh Implants and Injuries

108. Plaintiff Leah Smith was born on August 5, 1981. Plaintiff Leah Smith married Plaintiff Steven Smith in July of 2008.

109. On December 16, 2016, Dr. George Shashoua implanted Plaintiff Leah Smith with the Coloplast Restorelle XL 30x30cm and the Boston Scientific Advantage Fit.

110. Plaintiff Leah Smith was 35 years old when she was implanted with the Coloplast Restorelle XL and Boston Scientific Advantage fit devices.

111. On December 16, 2016, Dr. Shashoua also implanted Boston Scientific's Advantage Fit into Plaintiff Leah Smith. Dr. Shashoua dissected through Plaintiff Leah Smith's vagina at the level of the mid-urethra and implanted the Advantage Fit transvaginally using trocars that are provided in the kit from Boston Scientific. Dr. Shashoua used the trocars to force the Advantage Fit from the vaginal incisions into the suprapubic incisions. The tape was then brought out through the skin incisions during cystoscopy. The sling was tensioned, the plastic sheath was removed, and the sling was cut at the level of the skin.

112. During the Implant Procedure on December 16, 2016, Dr. Shashoua cut the Restorelle XL 30x30cm polypropylene mesh into a 24x6cm strip and implanted the mesh through the vagina (transvaginally) for correction of Plaintiff Leah Smith's posterior pelvic organ prolapse (rectocele). The proximal portion of the mesh was left in the rectovaginal space for retrieval later in the procedure. After suturing the Restorelle mesh transvaginally, Dr. Shashoua utilized the Da Vinci robot via abdominal dissection to access the mesh left in Plaintiff Leah Smith's posterior compartment during the transvaginal portion of the procedure. Dr. Shashoua located and delivered the posteriorly placed Restorelle mesh into the pelvis and anchored the posterior mesh to the posterior vagina. The fixation extended out laterally to fix the lateral vaginal at the level of the uterosacral ligaments. A similar size piece of Restorelle mesh (24x5cm) was introduced abdominally using the Da Vinci robot to correct Plaintiff Leah Smith's anterior pelvic organ prolapse (cystocele). Dr. Shashoua anchored the Restorelle mesh for the anterior repair to the

anterior vagina with fixation extending distally to the level of the bladder neck, laterally to the lateral vagina, and apically to the apex of the anterior vagina. Dr. Shashoua then joined the two large pieces of mesh by grasping both pieces, fashioning them over Plaintiff Leah Smith's sacrum, and anchored both pieces of mesh together to the sacral promontory.

113. Plaintiff Leah Smith returned to the operating room for a revision by Dr. Shashoua on April 3, 2017. During the procedure, Dr. Shashoua performed a bilateral salpingo-oopherectomy and then addressed the Advantage Fit Sling. According to the Operative Note, Dr. Shashoua identified the prior Advantage Fit Sling he had implanted and "freed and mobilized [it] away from the vagina and also away form the overlying urethra." Thereafter, Dr. Shashoua implanted a second Advantage Fit sling. The second Advantage Fit Sling was placed with increased tension and was lying slightly proximal to the previously placed sling.

114. The subsequent erosion, pain, mesh removal procedures and surgeries were caused by the Products implanted into Plaintiff Leah Smith. Plaintiff continues to suffer from mesh related complications and pain to the present day.

115. Plaintiff Leah Smith returned to the operation room for a second revision performed by Dr. Shashoua on October 1, 2018. During this procedure, Dr. Shashoua implanted the Coloplast Direct Fix mesh transvaginally to correct anterior prolapse.

116. Plaintiff Leah Smith returned to the operation room for a third revision performed by Dr. Shashoua on November 2, 2018. Prior to the procedure, Plaintiff Leah Smith was experiencing incomplete bladder emptying. During this procedure, Dr. Shashoua removed one of the prior Boston Scientific Advantage Fit slings from sulci to sulci. According to the operative note, "[t]he sling was fully mobilized laterally and then transected and then freed from the

overlying urethra and then excised lateral to the sulci bilaterally." This does not mean that the entire sling was removed, but only a small portion that existed under the urethra.

117. Plaintiff Leah Smith returned to the operating room for a fourth revision performed by Dr. Shashoua on October 19, 2019. Plaintiff Leah Smith's preoperative diagnosis for this surgery was "[d]yspareunia and nonspecific lower pelvic pain following prior vaginal mesh repair." This diagnoses was confirmed during the procedure. Dr. Shashoua performed a revision of the anterior vaginal mesh and subsequent anterior repair with cervicopexy. During this procedure, Dr. Shashoua identified the Coloplast Direct Fix device, and removed mesh using a dissection that extend laterally to expose the path of the mesh towards the sacrospinous ligaments. Dr. Shashoua took the distal section to the level of the bladder neck in removing Direct Fix mesh. Dr. Shashoua used a non-polypropylene biologic graft to reduce the bladder prolapse that was caused from removal of the Coloplast Direct Fix product.

118. On October 20, 2020, Leah Smith returned to the operating room for a fifth revision; however, this revision procedure was performed by Dr. Grady Bruce in Round Rock, TX. Prior to this revision surgery, Dr. Bruce diagnosed Leah Smith with dyspareunia, sexual pain and vaginal wound after anterior vaginal mesh and biologic graft surgeries. Dr. Bruce confirmed these diagnoses post-operatively. During the procedure, Dr. Bruce removed additional portions of the Coloplast mesh placed anteriorly and sutured the vaginal wound. Dr. Bruce found transverse anterior vaginal wall banding with dyspareunia, sexual pain, and vaginal scarification. According to pathology records, 5cm x 5cm (in aggregate) of Coloplast mesh was removed during this procedure.

119. As a result of being implanted with the Products, Plaintiff Leah Smith has experienced degradation of the polypropylene mesh and the pelvic tissue, chronic inflammation of

the pelvic tissue, mesh shrinkage or mesh contraction of the mesh causing chronic pain, mesh deformation causing chronic pain, nerve entrapment, chronic inflammation, chronic infectious response, chronic pain, pain while sitting, painful sexual relations, significant urinary dysfunction, vaginal shortening, vaginal and rectal anatomic deformation, and a severe adverse reactions to the mesh.

120. The Products implanted by Dr. Shashoua into Plaintiff Leah Smith have caused life-altering and permanent injuries to Plaintiff Leah Smith. Plaintiff Leah Smith has suffered severe emotional pain and injury and has suffered and will suffer apprehension of increased risk for injuries, infections, pain, mental anguish, infection, bodily disfigurement, and multiple corrective procedures/surgeries as a result of implantation of mesh. Plaintiff Leah Smith continues to suffer from mesh related complications and pain to this day that and, in a reasonable degree of medical probability, will continue for the remainder of her life. Plaintiff Leah Smith will need additional corrective procedures and surgeries due to injuries associated to the vaginal mesh Products implanted by Dr. Shashoua.

121. The Products implanted into Leah Smith are not safer or more effective as compared to available feasible alternative treatments for stress urinary incontinence and pelvic organ prolapse. Concerning correction of Plaintiff Leah Smith's stress urinary incontinence, there are other options instead of implantation of the Advantage Fit for treatment of SU including, but not limited to, autologous fascial sling or Burch procedure. Concerning correction of Plaintiff Leah Smith's pelvic organ prolapse, there are other options instead of implantation of the Coloplast Restorelle XL and Coloplast Direct Fix Anterior including, but not limited to, use of biologic materials resistant to contraction/shrinkage, native tissue repair, or potentially mesh via only abdominal approach that has a smaller footprint than what was used.

NEGLIGENCE OF DEFENDANT COLOPLAST CORP. AND DEFENDANT COLOPLAST MANUFACTURING US, LLC.

122. Plaintiffs incorporate by reference each and every paragraph of this Complaint as if fully set forth in this Count.

123. At all times material hereto, Defendant Coloplast had a duty to Plaintiff to exercise reasonable care in the design, manufacture, testing, inspection, processing, advertising, marketing, testing, labeling, assembling, packaging, distribution, warning, detailing, promotion and sale of its Restorelle and Direct Fix Anterior mesh devices.

124. Defendant Coloplast was negligent in that it failed to exercise reasonable care in the design, manufacture, testing, inspection, processing, advertising, marketing, testing, labeling, assembling, packaging, distribution, warning, detailing, promotion and sale of its Restorelle and Direct Fix Anterior mesh devices.

125. As a result of said failures, the Restorelle and Direct Fix Anterior brand mesh devices implanted in Plaintiff were unreasonably dangerous and defective in design and unaccompanied by adequate warnings concerning its hazardous properties.

126. The unreasonably dangerous condition, defects and inadequate warnings existed when the Restorelle and Direct Fix Anterior brand mesh devices implanted in Plaintiff left Defendant Coloplast's custody and control.

127. In addition, Defendant Coloplast had an obligation to issue a timely post-sale warning regarding risks that became known after it either first began marketing the Products and/or after Plaintiff was implanted with the Restorelle and Direct Fix Anterior brand mesh devices.

128. Defendant Coloplast was negligent in that they failed to exercise reasonable care in failing to issue a timely post-sale warning regarding risks that became known after it either first

began marketing the Products and/or after Plaintiff was implanted with the Restorelle and Direct Fix Anterior brand mesh devices.

129. At all times material, Defendant Coloplast failed to exercise reasonable care under the circumstances, as it knew, or in the exercise of reasonable care, should have known, that its Restorelle and Direct Fix Anterior brand mesh devices were not properly manufactured, compounded, assembled, inspected, packaged, distributed, tested, analyzed, examined, or prepared, such that the medical device was defective, unreasonably dangerous, and likely to injure its users, including Plaintiff Smith herein.

130. Also, Defendant Coloplast failed to exercise reasonable care under the circumstances, as it knew, or in the exercise of reasonable care, should have known, that its Restorelle and Direct Fix Anterior brand mesh device were sold without sufficient warnings or instruction (both before as well as after their sale), such that the Restorelle and Direct Fix Anterior brand mesh devices were likely to injure its users, including Plaintiff Smith herein.

131. Further, Defendant Coloplast failed to exercise reasonable care under the circumstances, as it knew, or in the exercise of reasonable care, should have known, that its Restorelle and Direct Fix Anterior brand mesh devices and the information (including warnings, instructions, detailing, advertising, promotion, and representations) about the characteristics and properties of the devices; the potential risks associated with their use in patients; safety and efficacy data; the attributes of the devices relative to other competing medical devices; and the management of patients after implantation of this devices were inaccurate or incomplete, such that the medical devices were likely to injure its users, including Plaintiff Smith herein.

132. Defendant Coloplast also failed to conduct sufficient testing, quality assurance measures and/or inspection of its Restorelle and Direct Fix Anterior brand mesh devices, both prior

to and after clearance of the products for sale, which, if properly performed, would have revealed or led, long ago, to the detection of defects in the Restorelle and Direct Fix Anterior brand mesh devices and inadequacy in the warnings, promotional materials and instructions which accompanied the devices, such that the injuries suffered by Plaintiff Smith herein could have been prevented.

133. These negligent acts by Defendant Coloplast resulted in the sale of Restorelle and Direct Fix Anterior brand mesh devices that were unreasonably dangerous, unsafe, and not reasonably fit for the uses and purposes for which the medical devices would ordinarily be put or some other reasonably foreseeable purpose and the unreasonably dangerous condition existed when such devices, including the particular devices implanted in Plaintiff, left Defendant Coloplast's custody and control.

134. Defendant Coloplast knew or should have known that the Restorelle and Direct Fix Anterior mesh devices subjected Plaintiff Smith to unreasonably dangerous risks of which the Plaintiff Smith and her treating physicians would not be aware. Nevertheless, Defendant Coloplast advertised, marketed, sold and distributed the Restorelle and Direct Fix Anterior brand mesh devices for years to thousands of women, at a time when Defendant Coloplast knew that there were safer methods and products available for the treatment of pelvic organ prolapse and stress urinary incontinence.

135. Had Plaintiff Smith, her treating physician, or both known of the unreasonably dangerous risks associated with the Restorelle and Direct Fix Anterior brand mesh devices at the time of her implant surgery, such knowledge would have affected the treating physician's use of the device and Plaintiff Smith would not have consented to the implantation of the devices.

136. By October of 2018, Defendant Coloplast was aware of increase adverse events and injuries associated with the implantation of the Direct Fix Anterior device. However, Defendant Coloplast did not inform Dr. Shashoua, Leah Smith, or the medical community of the injuries being reported in its 522 Post Market Study of the Direct Fix Anterior Product.

- **OFF-LABEL PROMOTION OF RESTORELLE XL**

137. Defendant Coloplast's negligence associated to Restorelle XL's warnings, instructions, detailing, advertising, promotion, and representations is shown through Coloplast's off-label promotion of Restorelle XL to Dr. Shashoua.

138. Defendant Coloplast's negligence in the sale and distribution of Restorelle XL is shown in Coloplast's off-label promotion of Restorelle XL to Dr. Shashoua.

139. Coloplast marketed and promoted Restorelle XL for "off-label" use to Dr. Shashoua despite knowing that use of Restorelle XL in applications not indicated by the label increase risk of injury to the patient.

140. Coloplast maintains knowledge that if Restorelle XL mesh is implanted transvaginally for correction of rectocele, the patient is exposed to an unreasonable risk of injury. Coloplast knows that transvaginal implantation of Restorelle XL mesh for the correction of rectocele is neither safer nor more efficacious than native tissue repair to correct rectocele.

141. In the wake of the FDAs 522 Orders on all Coloplast's transvaginal mesh products (including Restorelle XL products implanted transvaginally), in 2013 Coloplast contacted the FDA and requested to narrow indications for use of Restorelle XL, seeking to remove from the label the indication for implanting Restorelle XL by the vaginal route. On August 2, 2013, based on Coloplast request, the FDA narrowed the label for Restorelle XL,

removing Restorelle XL's indication for implantation through the vagina and only indicating the product for implantation in abdominal procedures.

142. From August 2, 2013 to present, Coloplast has marketed and promoted Restorelle XL for "off-label" use to Dr. Shashoua for implantation through the vagina to correct rectocele.

143. Coloplast knew at the time that Leah Smith was implanted with Restorelle XL that Dr. Shashoua was using Restorelle XL "off-label" when he implanted Restorelle XL through the vagina for correction of rectocele. Coloplast intended for Dr. Shashoua to use Restorelle XL "off-label" based on Coloplast's promotion of Restorelle XL to Dr. Shashoua and Coloplast's oral and written statements made to Dr. Shashoua concerning his use of Restorelle XL.

144. Between August 2, 2013 and October 1, 2018 (date that Dr. Shashoua the second Coloplast Transvaginal Product), Coloplast received many complaints identifying adverse events associated with Dr. Shashoua's implantation of Restorelle XL and Direct Fix Anterior transvaginally for the correction of pelvic organ prolapse. However, Coloplast did not inform Dr. Shashoua of the adverse events and injuries associated to the Restorelle XL or Direct Fix Anterior.

145. Despite Coloplast's knowledge that Dr. Shashoua was implanting Restorelle XL for off-label use and Coloplast's knowledge of adverse events associated with implanting Restorelle XL transvaginally, Coloplast made several failures, including but not limited to:

a. Coloplast never informed Dr. Shashoua of the adverse events Coloplast became aware of between 2013 and 2018 in patients he implanted Restorelle XL or Direct Fix Anterior transvaginally for the correction of POP.

b. Coloplast never issued Dr. Shashoua a prominent statement notifying Dr. Shashoua that his use of Restorelle XL for the correction of POP was no longer cleared by the FDA as a safe and effective use of the product.

c. Coloplast never informed Dr. Shashoua that Restorelle XL would have been subject to the FDA's 522 Orders had Coloplast not sought to narrow the indication in the instructions for use, removing the indication for implantation via the vaginal route.

d. Coloplast never told Dr. Shashoua his off-label use of Restorelle XL exposed Leah Smith and other patients, to an unreasonable risk of injury.

e. Coloplast never told Dr. Shashoua that his off-label use of Restorelle XL was neither safer nor more efficacious than native tissue repair to correct rectocele.

146. Coloplast's off-label promotion of Restorelle XL to Dr. Shashoua resulted in injuries to Plaintiff Leah Smith.

147. As a direct and proximate result of the defective condition of the Coloplast Restorelle and Direct Fix Anterior vaginal mesh, including but not limited to the wrongful acts, negligence, omissions and fraudulent representations of Defendant Coloplast, Plaintiff has suffered serious and permanent injuries, including pain and suffering, loss of capacity for the enjoyment of life, pelvic and vaginal pain and suffering, complex extrusion and erosion of the mesh in her body, chronic inflammation with swollen inflamed tissue in her vagina, mesh adhesion to her vagina and surrounding tissue, tissue damage and death of her vaginal wall tissue and nerves, failure of the mesh to treat her underlying conditions, new onset urinary and pelvic complications, mesh deformation including coiling, contracting, shrinkage, pore collapse and curling of the mesh inside her vagina, mesh hardening and stiffening, intervention for her pain including the need for painful surgical interventions to remove segments of the eroded mesh, as well as the need for continuing and future medical care and treatment, and the medical probability of additional mesh related surgeries in the future. Plaintiff Smith has incurred significant expenses for medical care and treatment and will continue to incur such expenses in the future.

148. As a direct, proximate and foreseeable result of Defendants' negligence, Plaintiff has been damaged in an amount to be determined at trial.

NEGLIGENCE OF DEFENDANT BOSTON SCIENTIFIC CORP.

149. Plaintiffs incorporate by reference each and every paragraph of this Complaint as if fully set forth in this Count.

150. At all times material hereto, Defendant Boston Scientific had a duty to Plaintiff to exercise reasonable care in the design, manufacture, testing, inspection, processing, advertising, marketing, testing, labeling, assembling, packaging, distribution, warning, detailing, promotion and sale of its Advantage Fit mesh devices.

151. Defendant Boston Scientific was negligent in that it failed to exercise reasonable care in the design, manufacture, testing, inspection, processing, advertising, marketing, testing, labeling, assembling, packaging, distribution, warning, detailing, promotion and sale of its Advantage Fit mesh devices.

152. As a result of said failures, the Advantage Fit device implanted in Plaintiff were unreasonably dangerous and defective in design and unaccompanied by adequate warnings concerning its hazardous properties.

153. The unreasonably dangerous condition, defects and inadequate warnings existed when the Advantage Fit device left Defendant Boston Scientific's custody and control.

154. In addition, Defendant Boston Scientific had an obligation to issue a timely post-sale warning regarding risks that became known after it either first began marketing the Products and/or after Plaintiff was implanted with Advantage Fit brand mesh devices.

155. Defendant Boston Scientific had an obligation to only use true Marlex mesh in the Advantage Fit Device and was negligent when it chose to purchase counterfeit polypropylene from China to use in the Advantage Fit Device. Defendant Boston Scient knew, or should have known, that failing to use true Marlex mesh would expose Plaintiff Smith to injury.

156. Defendant Boston Scientific was negligent in that they failed to exercise reasonable care in failing to issue a timely post-sale warning regarding risks that became known after it either first began marketing the Products and/or after Plaintiff was implanted with the Advantage Fit mesh devices.

157. Defendant Boston Scientific was negligent for not informing Dr. Shashoua that implanting two midurethral slings to correct stress urinary incontinence increased the risk of injury or adverse events associated to the products.

158. At all times material, Defendant Boston Scientific failed to exercise reasonable care under the circumstances, as it knew, or in the exercise of reasonable care, should have known, that the Advantage Fit brand mesh devices was not properly manufactured, compounded, assembled, inspected, packaged, distributed, tested, analyzed, examined, or prepared, such that the medical device was defective, unreasonably dangerous, and likely to injure its users, including Plaintiff Smith herein.

159. Also, Defendant Boston Scientific failed to exercise reasonable care under the circumstances, as it knew, or in the exercise of reasonable care, should have known, that Advantage Fit devices were sold without sufficient warnings or instruction (both before as well as after their sale), such that the Advantage Fit devices were likely to injure its users, including Plaintiff Smith herein.

160. Further, Defendant Boston Scientific failed to exercise reasonable care under the circumstances, as it knew, or in the exercise of reasonable care, should have known, that its Advantage Fit mesh devices and the information (including warnings, instructions, detailing, advertising, promotion, and representations) about the characteristics of the devices did not provide proper notice of injury/warnings, including failing to appropriately provide the potential

risks associated with their use in patients; safety and efficacy data; the attributes of the devices relative to other competing medical devices; and the management of patients' injuries after implantation of this devices were inaccurate or incomplete, such that the medical devices were likely to injure its users, including Plaintiff Smith herein.

161. Defendant Boston Scientific also failed to conduct sufficient testing, quality assurance measures and/or inspection of its Advantage Fit mesh devices, both prior to and after clearance of the products for sale, which, if properly performed, would have revealed or led, long ago, to the detection of defects in the Advantage Fit mesh devices and inadequacy in the warnings, promotional materials and instructions which accompanied the devices, such that the injuries suffered by Plaintiff Smith herein could have been prevented.

162. These negligent acts by Defendant Boston Scientific resulted in the sale of Advantage Fit brand mesh devices that were unreasonably dangerous, unsafe, and not reasonably fit for the uses and purposes for which the medical devices would ordinarily be put or some other reasonably foreseeable purpose and the unreasonably dangerous condition existed when such devices, including the particular devices implanted in Plaintiff, left Defendant Boston Scientific's custody and control.

163. Defendant Boston Scientific knew or should have known that the Advantage Fit device subjected Plaintiff Smith to unreasonably dangerous risks of which the Plaintiff Smith and her treating physicians would not be aware. Nevertheless, Defendant Boston Scientific advertised, marketed, sold and distributed the Advantage Fit mesh devices for years to thousands of women, at a time when Defendant Boston Scientific knew that there were safer methods and products available for the treatment of pelvic organ prolapse and stress urinary incontinence.

164. Had Plaintiff Smith, her treating physician, or both known of the unreasonably dangerous risks associated with the Advantage Fit brand devices at the time of her implant surgeries, such knowledge would have affected the treating physician's use of the device and Plaintiff Smith would not have consented to the implantation of the devices.

NEGLIGENT MISREPRESENTATION OF DEFENDANT COLOPLAST CORP. AND DEFENDANT COLOPLAST MANUFACTURING US, LLC.

165. Plaintiff Smith repeats and realleges all allegations contained in this Complaint as if fully set forth in this Count.

166. Defendant Coloplast had a duty to accurately and truthfully represent to the medical and healthcare community, and to Plaintiff Smith and the general public, that the Products had not been adequately tested and found to be safe and effective for the treatment of female pelvic organ prolapse and stress urinary incontinence.

167. The representations made by Defendant Coloplast were, in fact, false.

168. Defendant Coloplast failed to exercise ordinary care in the representation of the Products, while involved in its manufacture, sale, testing, quality assurance, quality control, and/or distribution of said Products into interstate commerce in that Defendant Coloplast negligently misrepresented the Products' high risk of unreasonable, dangerous side effects.

169. Defendant Coloplast breached their duty in misrepresenting the Products' serious side effects to the medical and healthcare community, Plaintiff Smith, Plaintiff Smith's physicians, and the public in general.

170. By October of 2018, Defendant Coloplast was aware of increase adverse events and injuries associated with the implantation of the Direct Fix Anterior device. However, Defendant Coloplast did not inform Dr. Shashoua, Leah Smith, or the medical community of the injuries being reported in its 522 Post Market Study of the Direct Fix Anterior Product.

- **OFF-LABEL PROMOTION OF RESTORELLE XL**

171. Defendant Coloplast's negligent misrepresentations associated to the sale and distribution of Restorelle XL is shown in Coloplast's off-label promotion of Restorelle XL to Dr. Shashoua.

172. Coloplast marketed and promoted Restorelle XL for "off-label" use to Dr. Shashoua despite knowing that use of Restorelle XL in applications not indicated by the label increase risk of injury to the patient.

173. Coloplast maintains knowledge that if Restorelle XL mesh is implanted transvaginally for correction of rectocele, the patient is exposed to an unreasonable risk of injury. Coloplast knows that transvaginal implantation of Restorelle XL mesh for the correction of rectocele is neither safer nor more efficacious than native tissue repair to correct rectocele.

174. In the wake of the FDAs 522 Orders on all Coloplast's transvaginal mesh products (including Restorelle products implanted transvaginally), in 2013 Coloplast contacted the FDA and requested to narrow indications for use of Restorelle XL, seeking to remove from the label the indication for implanting Restorelle XL by the vaginal route. On August 2, 2013, based on Coloplast request, the FDA narrowed the label for Restorelle XL, removing Restorelle XL's indication for implantation through the vagina and only indicating the product for implantation in abdominal procedures.

175. From August 2, 2013 to present, Coloplast has marketed and promoted Restorelle XL for "off-label" use to Dr. Shashoua for implantation through the vagina to correct rectocele.

176. Coloplast knew at the time that Leah Smith was implanted with Restorelle XL that Dr. Shashoua was using Restorelle XL "off-label" when he implanted Restorelle XL through the vagina for correction of rectocele. Coloplast intended for Dr. Shashoua to use

Restorelle XL "off-label" based on Coloplast's promotion of Restorelle XL to Dr. Shashoua and Coloplast's oral and written statements made to Dr. Shashoua concerning his use of Restorelle XL.

177. Between August 2, 2013 and April 3, 2017, Coloplast received many complaints identifying adverse events associated with Dr. Shashoua's implantation of Restorelle XL transvaginally for the correction of rectocele.

178. Despite Coloplast's knowledge that Dr. Shashoua was implanting Restorelle XL for off-label use and Coloplast's knowledge of adverse events associated with implanting Restorelle XL transvaginally, Coloplast made several failures, including but not limited to:

a. Coloplast never informed Dr. Shashoua of the adverse events Coloplast became aware of between 2013 and 2019 in patients he implanted Restorelle XL transvaginally for the correction of rectocele.

b. Coloplast never issued Dr. Shashoua a prominent statement notifying Dr. Shashoua that his use of Restorelle XL for correction of rectocele was no longer cleared by the FDA as a safe and effective use of the product.

c. Coloplast never informed Dr. Shashoua that Restorelle XL would have been subject to the FDA's 522 Orders had Coloplast not sought to narrow the indication in the instructions for use, removing the indication for implantation via the vaginal route.

d. Coloplast never told Dr. Shashoua his off-label use of Restorelle XL exposed Leah Smith and other patients, to an unreasonable risk of injury.

e. Coloplast never told Dr. Shashoua that his off-label use of Restorelle XL was neither safer nor more efficacious than native tissue repair to correct rectocele.

179. Coloplast's off-label promotion of Restorelle XL to Dr. Shashoua resulted in injuries to Plaintiff Leah Smith.

180. As a foreseeable, direct and proximate result of the negligent misrepresentation of Defendant Coloplast as set forth herein, Defendant Coloplast knew, and had reason to know, that the Restorelle and Direct Fix Anterior had been insufficiently tested, or had not been tested at all,

and that it lacked adequate and accurate warnings, and that it created a high risk, and/or higher than acceptable risk, and/or higher than reported and represented risk, of adverse side effects, including, erosion, pain and suffering, surgery to remove the Restorelle and Direct Fix Anterior, and other severe and personal injuries, which are permanent and lasting in nature. Coloplast also continued to contact Dr. Shashoua, promoting and marketing Restorelle XL for off-label use of Restorelle XL by Dr. Shashoua.

181. As a direct and proximate result of the Defendant Coloplast's negligent misrepresentations, Plaintiff Smith has suffered serious and permanent bodily injuries, including pain and suffering, loss of capacity of the enjoyment of life, pelvic and vaginal pain and suffering, complex extrusion and erosion of the mesh in her body, chronic inflammation with swollen inflamed tissue in her vagina, mesh adhesion to her vagina and surrounding tissue, tissue damage and death of her vaginal wall tissue and nerves, failure of the mesh to treat her underlying conditions, new onset urinary and pelvic complications, mesh deformation including coiling, contracting, pore collapse, and curling of the mesh insider her vagina, mesh hardening and stiffening, vaginal deformation, intervention for her pain including the need for painful surgical interventions to remove segments of the Products, as well as the need for continuing and future medical care and treatment. She has incurred significant expenses for medical care and treatment and will continue to incur such expenses in the future.

NEGLIGENT MISREPRESENTATION OF BOSTON SCIENTIFIC CORP.

182. Plaintiff Smith repeats and realleges all allegations contained in this Complaint as if fully set forth in this Count.

183. Defendant Boston Scientific represented that the Advantage Fit was safe and effective for correction of stress urinary incontinence despite never testing the products inside the human body before they were cleared to market.

184. Defendant Boston Scientific had a duty to accurately and truthfully represent to the medical and healthcare community, and to Plaintiff Smith and the general public, that the Products had not been adequately tested and found to be safe and effective for the treatment of female pelvic organ prolapse and stress urinary incontinence. This is especially true pertaining to the counterfeit Marlex purchased by Boston Scientific and used in the Advantage Fit products implanted into Leah Smith.

185. Defendant Boston Scientific failed to exercise ordinary care in the representation of the Advantage Fit products, while involved in its manufacture, sale, testing, quality assurance, quality control, and/or distribution of said products into interstate commerce in that Defendant Boston Scientific negligently misrepresented the products' high risk of unreasonable, dangerous side effects.

186. Defendant Boston Scientific breached their duty in misrepresenting the Advantage Fit's serious side effects to the medical and healthcare community, Plaintiff Smith, Plaintiff Smith's physicians, and the public in general.

187. Defendant Boston Scientific negligently represented that more than one Advantage Fit slings could be implanted into same woman without an increased risk of injury or mesh related adverse event. Indeed, Dr. Shashoua implanted two Advantage Fit slings into Leah Smith based on this representation.

- **Promotion of Counterfeit Mesh Used in Advantage Fit**

188. Defendant Boston Scientific's negligent misrepresentations associated to the sale and distribution of the Advantage Fit is shown in its promotion of the Advantage Fit made from counterfeit Marlex.

189. As shown above, Boston Scientific knew, or at the very least should have known, that the Marlex purchased from China to use in the Advantage Fit sling implanted into Leah Smith was not true Marlex. Boston Scientific negligently represented to doctors and to Leah Smith that the Advantage Fit Product was properly cleared for use and made from Marlex, when it was not.

190. Boston Scientific maintains knowledge that the properties of its mesh products, including the type of polypropylene used, can impact patient safety and cause increased risk of patient injury. However, Boston Scientific never informed the Dr. Shashoua, the public, or Leah Smith that its products were being made from counterfeit mesh.

191. The properties of the sling used with counterfeit Chinese mesh increase the chance that an injury will occur. Ultimately the propertives of the coutnerfiet Chinese mesh caused injury to Plaintiff Smith.

- **Boston Scientific Withheld Safety Information**

192. Boston Scientific never informed Dr. Shashoua of the adverse events it was became aware of between 2013 and 2019 in patients he implanted Advantage Fit products into. However, Boston Scientific did represent to Dr. Shashoua that his use of the Advantage Fit slings was safe and effective.

193. As a foreseeable, direct and proximate result of the negligent misrepresentation of Defendant Boston Scientific set forth herein, Defendant Boston Scientific knew, and had reason

to know, that the Advantage Fit had been insufficiently tested, or had not been tested at all, and that it lacked adequate and accurate warnings, and that it created a high risk, and/or higher than acceptable risk, and/or higher than reported and represented risk, of adverse side effects, including, erosion, mesh degradation, pain and suffering, surgery to remove the Advantage Fit, and other severe and personal injuries, which are permanent and lasting in nature.

194. As a direct and proximate result of the Defendant Boston Scientific's negligent misrepresentations, Plaintiff Smith has suffered serious and permanent bodily injuries, including pain and suffering, loss of capacity of the enjoyment of life, pelvic and vaginal pain and suffering, complex extrusion and erosion of the mesh in her body, chronic inflammation with swollen inflamed tissue in her vagina, mesh adhesion to her vagina and surrounding tissue, tissue damage and death of her vaginal wall tissue and nerves, failure of the mesh to treat her underlying conditions, new onset urinary and pelvic complications, mesh deformation including coiling, contracting, pore collapse, and curling of the mesh insider her vagina, mesh hardening and stiffening, vaginal deformation, intervention for her pain including the need for painful surgical interventions to remove segments of the Advantage Fit, as well as the need for continuing and future medical care and treatment. She has incurred significant expenses for medical care and treatment and will continue to incur such expenses in the future.

GROSS NEGLIGENCE OF DEFENDANT COLOPLAST CORP. AND DEFENDANT COLOPLAST MANUFACTURING US, LLC.

195. Plaintiff Smith repeats and realleges all allegations contained in all paragraphs above as if fully set forth in this Count.

196. In committing the acts and/or omissions set forth herein that directly and proximately caused Plaintiff Smith's injuries, as set forth herein, Defendant Coloplast breached its

duty to Plaintiff and demonstrated a conscious, reckless, willful and wanton indifference to and disregard of the consequences of its actions and/or omissions.

197. Defendant Coloplast was grossly negligent by showing a complete indifference for the safety and health of Plaintiff and others similarly situated, in negligently designing, packaging, labeling, marketing, advertising, promoting, distributing and selling a defective and unreasonably dangerous products and in negligently failing to warn Plaintiff of the significant risks and complications associated with its device, as set forth above.

198. Defendant Coloplast was grossly negligent in by showing a complete indifference for the safety and health of Plaintiff Smith and others similarly situated, in negligently continuing to sell polypropylene products for vaginal implantation despite decades of evidence that the products were unreasonably dangerous.

199. In light of the knowledge Defendant Coloplast had concerning the risks and complications associated with its devices, as set forth above, Defendants continued to show an utter disregard and complete indifference for the safety of Plaintiff Smith by failing to provide adequate warnings concerning the risks and complications associated with its pelvic organ prolapse device, making material misrepresentations and placing profits from sales of its device over the safety of patients receiving its device.

200. Coloplast marketed and promoted Restorelle XL for "off-label" use to Dr. Shashoua despite knowing that use of Restorelle XL in applications not indicated by the label increase risk of injury to the patient.

201. Coloplast maintains knowledge that if either the Restorelle XL or Direct Fix Anterior mesh products are implanted vaginally for correction of pelvic organ prolapse, the patient is exposed to an unreasonable risk of injury. Coloplast knows that transvaginal

implantation of Restorelle XL and/or Direct Fix Anterior mesh for the correction of POP is neither more safe nor more efficacious than native tissue repair to correct rectocele.

202. In the wake of the FDAs 522 Orders on all Coloplast's transvaginal mesh products (including Restorelle XL and Direct Fix Anterior products implanted transvaginally), Coloplast contacted the FDA in 2013 and requested to narrow indications for use of Restorelle XL, seeking to remove from the label the indication for implanting Restorelle XL by the vaginal route. On August 2, 2013, based on Coloplast request, the FDA narrowed the label for Restorelle XL, removing Restorelle XL's indication for implantation through the vagina and only indicating the product for implantation in abdominal procedures.

203. From August 2, 2013 to present, Coloplast has marketed and promoted Restorelle XL for "off-label" use to Dr. Shashoua for implantation through the vagina to correct rectocele.

204. Coloplast knew at the time that Leah Smith was implanted with Restorelle XL that Dr. Shashoua was using Restorelle XL "off-label" when he implanted Restorelle XL through the vagina for correction of rectocele. Coloplast intended for Dr. Shashoua to use Restorelle XL "off-label" based on Coloplast's promotion of Restorelle XL to Dr. Shashoua and Coloplast's oral and written statements made to Dr. Shashoua concerning his use of Restorelle XL.

205. Between August 2, 2013 and April 3, 2017 (date that Dr. Shashoua implanted Restorelle XL transvaginally for the correction of Leah Smith's rectocele), Coloplast received many complaints identifying adverse events associated with Dr. Shashoua's implantation of Restorelle XL transvaginally for the correction of rectocele.

206. Despite Coloplast's knowledge that Dr. Shashoua was implanting Restorelle XL for off-label use and Coloplast's knowledge of adverse events associated with implanting Restorelle XL transvaginally, Coloplast made several failures, including but not limited to:

a. Coloplast never informed Dr. Shashoua of the adverse events Coloplast became aware of between 2013 and 2019 in patients he implanted Restorelle XL transvaginally for the correction of rectocele.

b. Coloplast never issued Dr. Shashoua a prominent statement notifying Dr. Shashoua that his use of Restorelle XL for correction of rectocele was no longer cleared by the FDA as a safe and effective use of the product.

c. Coloplast never informed Dr. Shashoua that Restorelle XL would have been subject to the FDA's 522 Orders had Coloplast not sought to narrow the indication in the instructions for use, removing the indication for implantation via the vaginal route.

d. Coloplast never told Dr. Shashoua his off-label use of Restorelle XL exposed Leah Smith and other patients, to an unreasonable risk of injury.

e. Coloplast never told Dr. Shashoua that his off-label use of Restorelle XL was neither safer nor more efficacious than native tissue repair to correct rectocele.

207. Coloplast's off-label promotion of Restorelle XL to Dr. Shashoua resulted in injuries to Plaintiff Leah Smith.

208. Coloplast's failure to inform Dr. Shashoua of adverse events related to the Restorelle XL and the Direct Fix Anterior products was grossly negligent and willful. Coloplast sought to maintain sells of these products at the risk of exposing Leah Smith, and others like her in Central Texas, to increased risk of adverse events and dangerous injuries.

209. The wrongs done by Defendant Coloplast were aggravated by the kind of malice, fraud, and grossly negligent disregard for the rights of others, the public, and Plaintiff for which the law would allow, and for which Plaintiff seeks exemplary damages, in that Defendant Coloplast's conduct, including the failure to comply with applicable industry standards was specifically intended to cause substantial injury to Plaintiff; or when viewed objectively from

Defendant Coloplast's standpoint at the time of the conduct, involved an extreme degree of risk, considering the probability and magnitude of the potential harm to others, including Plaintiff Smith, and Defendant Coloplast was actually, subjectively aware of the risk involved, but nevertheless proceeded with conscious indifference to the rights, safety, or welfare of others, including Plaintiff Smith; or included a material representation that was false, with Defendant Coloplast knowing that it was false or with reckless disregard as to its truth and as a positive assertion, with the intent that the representation is acted on by Plaintiff Smith.

210. As a direct and proximate result of the Defendant Coloplast's gross negligence, Plaintiff Smith has suffered serious and permanent injuries, including pain and suffering, loss of capacity for the enjoyment of life, pelvic and vaginal pain, complex extrusion and erosion of the mesh in her body, chronic inflammation with swollen inflamed tissue in her vagina, mesh adhesion to her vagina and surrounding tissue, tissue damage and death of her vaginal wall tissue and nerves, failure of the mesh to treat her underlying conditions, new onset, urinary and pelvic complications, mesh deformation including coiling, contracting and curling of the mesh insider her vagina, mesh hardening and stiffening, intervention for her pain including the need for painful surgical interventions to remove segments portions of both Products, as well as the need for continuing and future medical care and treatment. Plaintiff Smith has incurred significant expenses for medical care and treatment and will continue to incur such expenses in the future.

GROSS NEGLIGENCE OF DEFENDANT BOSTON SCIENTIFIC CORP.

211. Plaintiff Smith repeats and realleges all allegations contained in all paragraphs above as if fully set forth in this Count.

212. In committing the acts and/or omissions set forth herein that directly and proximately caused Plaintiff Smith's injuries, as set forth herein, Defendant Boston Scientific

breached its duty to Plaintiff and demonstrated a conscious, reckless, willful and wanton indifference to and disregard of the consequences of its actions and/or omissions.

213. Defendant Boston Scientific was grossly negligent by showing a complete indifference for the safety and health of Plaintiff and others similarly situated, in negligently designing, packaging, labeling, marketing, advertising, promoting, distributing and selling a defective and unreasonably dangerous products and in negligently failing to warn Plaintiff of the significant risks and complications associated with its device, as set forth above.

214. Defendant Boston Scientific was grossly negligent in by showing a complete indifference for the safety and health of Plaintiff Smith and others similarly situated, in negligently continuing to sell polypropylene products for vaginal implantation despite decades of evidence that the products were unreasonably dangerous.

215. In light of the knowledge Defendant Boston Scientific had concerning the risks and complications associated with its devices, as set forth above, Defendants continued to show an utter disregard and complete indifference for the safety of Plaintiff Smith by failing to provide adequate warnings concerning the risks and complications associated with its pelvic organ prolapse device, making material misrepresentations and placing profits from sales of its device over the safety of patients receiving its device.

216. Boston Scientific's failure to inform Dr. Shashoua of adverse events related to the Advantage Fit products was grossly negligent and willful. Boston Scientific sought to maintain sells of these products at the risk of exposing Leah Smith, and others like her in Central Texas, to increased risk of adverse events and dangerous injuries.

217. The wrongs done by Defendant Boston Scientific were aggravated by the kind of malice, fraud, and grossly negligent disregard for the rights of others, the public, and Plaintiff for

which the law would allow, and for which Plaintiff seeks exemplary damages, in that Defendant Boston Scientific's conduct, including the failure to comply with applicable industry standards was specifically intended to cause substantial injury to Plaintiff; or when viewed objectively from Defendant Boston Scientific's standpoint at the time of the conduct, involved an extreme degree of risk, considering the probability and magnitude of the potential harm to others, including Plaintiff Smith, and Defendant Boston Scientific was actually, subjectively aware of the risk involved, but nevertheless proceeded with conscious indifference to the rights, safety, or welfare of others, including Plaintiff Smith; or included a material representation that was false, with Defendant Boston Scientific knowing that it was false or with reckless disregard as to its truth and as a positive assertion, with the intent that the representation is acted on by Plaintiff Smith.

218. As a direct and proximate result of the Defendant Boston Scientific's gross negligence, Plaintiff Smith has suffered serious and permanent injuries, including pain and suffering, loss of capacity for the enjoyment of life, pelvic and vaginal pain, complex extrusion and erosion of the mesh in her body, chronic inflammation with swollen inflamed tissue in her vagina, mesh adhesion to her vagina and surrounding tissue, tissue damage and death of her vaginal wall tissue and nerves, failure of the mesh to treat her underlying conditions, new onset, urinary and pelvic complications, mesh deformation including coiling, contracting and curling of the mesh insider her vagina, mesh hardening and stiffening, intervention for her pain including the need for painful surgical interventions to remove segments portions of both Products, as well as the need for continuing and future medical care and treatment. Plaintiff Smith has incurred significant expenses for medical care and treatment and will continue to incur such expenses in the future.

STRICT LIABILITY – DESIGN DEFECT AGAINST DEFENDANT COLOPLAST CORP. AND DEFENDANT COLOPLAST MANUFACTURING US, LLC. AND DEFENDANT BOSTON SCIENTIFIC CORP.

219. Plaintiff Smith repeats and realleges all allegations contained in this Complaint as if fully set forth in this Count.

220. At all times relevant herein, Defendant Coloplast and Defendant Boston Scientific were responsible for designing, developing, manufacturing, testing, packaging, promoting, marketing, distributing, labeling, and/or selling the respective Products at issue in this case.

221. The Products, as designed, were not reasonably safe because there was substantial likelihood of harm and it was feasible to design the product in a safe manner.

222. The unique design features of Products, as described in the detail herein, rendered the devices unsafe.

223. Practical, feasible alternative designs were possible and economically and technologically feasible at the time of the manufacture of Products implanted through the Plaintiff's vagina.

224. Other manufacturers of similar treatments and products had already put safer alternatives into use at the time of Defendant Coloplast and Defendant Boston Scientific's manufacture of the Products implanted in Plaintiff.

225. These safer alternatives would have prevented, minimized or significantly reduced the risks associated with the unique design features of the Products, eliminated the risks associated with the unique design features, and eliminated or reduced the frequency, severity, and duration of the risks associated with the Products without impairing the reasonably anticipated or intended function of the Products.

226. At all times relevant herein, Defendant Coloplast and Defendant Boston Scientific expected the Products to reach, and in fact did reach, consumers in Texas and throughout the United States without substantial change in the condition in which it was sold.

227. At all times relevant herein, Defendant Coloplast and Defendant Boston Scientific intended for their Products to be surgically implanted through the vagina into members of the general public, including Plaintiff Smith, and knew or should have known that the Products would be surgically implanted into members of the general public, including Plaintiff Smith.

228. The implantation of the Products into Plaintiff was reasonably foreseeable, and it was used in the manner for which it was intended by the Defendants.

229. At all times relevant herein, the Products were designed, developed, manufactured, tested, packaged, promoted, marketed, distributed, labeled, and/or sold by Defendant Coloplast and Defendant Boston Scientific in a defective and unreasonably dangerous condition at the time they were placed in the stream of commerce in ways which include, but are not limited to, one or more of the following:

a) When placed in the stream of commerce, the Products contained unreasonably dangerous design defects and was not reasonably safe as intended to be used, subjecting individuals, including Plaintiff, to risks that exceeded the benefit of the Products, including but not limited to the risks of developing serious and dangerous side effects, serious infection, the need for additional procedures to remove and replace the Products, and/or the need for additional surgery as well as other severe and permanent health consequences;

a. When placed in the stream of commerce, the Products were defective in design, making the use of the Products more dangerous than an ordinary consumer would expect, and more dangerous than other risks associated with alternatives;

b. The Products' design defects existed before they left the control of Defendants;

c. The Products were insufficiently tested;

d. The Products caused harmful side effects that outweighed any potential utility; and

e. The Products were not accompanied by adequate instruction and/or warnings to fully apprise consumers, including Physicians and the Plaintiff herein, of the full nature and extent of the risks and side effects associated with their use, thereby rendering the Defendants liable to Plaintiff.

230. As a direct and proximate result of Defendant Coloplast and Defendant Boston Scientific's defective design of the Products, Plaintiff has suffered serious and permanent injuries, including pain and suffering, loss of capacity for the enjoyment of life, pelvic and vaginal pain, complex extrusion and erosion of the mesh in her body, chronic inflammation with swollen inflamed tissue in her vagina, mesh adhesion to her vagina and surrounding tissue, tissue damage and death of her vaginal wall tissue and nerves, failure of the mesh to treat her underlying conditions, new onset of urinary and pelvic complications, mesh deformation including coiling, contracting and curling of the mesh insider her vagina, mesh hardening and stiffening, intervention for her pain including the need for painful surgical interventions to mesh, as well as the need for continuing and future medical care and treatment. She has incurred significant expenses for medical care and treatment and will continue to incur such expenses in the future.

STRICT LIABILITY – FAILURE TO WARN AGAINST DEFENDANT COLOPLAST CORP., DEFENDANT COLOPLAST MANUFACTURING US, LLC. AND DEFENDANT BOSTON SCIENTIFIC

231. Plaintiff Smith repeats and realleges all allegations contained in this Complaint as if fully set forth in this Count.

232. Defendant Coloplast and Defendant Boston Scientific were under a duty to disclose to Plaintiff and her physicians the defective nature of the Products, including, but not limited to, the heightened risks of erosion, pain, failure, and permanent injury, and the design characteristics which exacerbated or created unreasonable risks, and material safety information about the device.

233. In representations to Plaintiff Smith and/or to Plaintiff Smith's healthcare providers, Defendant Coloplast and Defendant Boston Scientific failed to warn about the following risks, and others, involved with the use of the Products:

a. That the Products were not as safe as other products, treatments and procedures available to pelvic organ prolapse and stress urinary incontinence;

b. That the risk of adverse events with the Products was higher than with other products, treatments and procedures available to treat pelvic organ prolapse;

c. The Products were not adequately tested;

d. That Defendant Coloplast and Defendant Boston Scientific deliberately failed to follow up on the adverse results from formal and informal reports from physicians and other healthcare providers and buried and/or misrepresented those findings;

e. That Defendant Coloplast and Defendant Boston Scientific were aware of dangers in the Products in addition to and above and beyond those associated with other products, treatments and procedures available to treat pelvic organ prolapse and Stress Urinary Incontinence;

f. That the Defendant Coloplast and Defendant Boston Scientific's Products at issue were defective, and caused dangerous and adverse side effects, including but not limited to higher incidence of erosions, extrusions, adverse tissue response and rejection, contraction, migration, trauma, groin pain, vaginal pain, failure, and revision surgeries at a much more significant rate than other products, treatments and procedures available to treat pelvic organ prolapse and stress urinary incontinence;

g. That patients needed to be monitored more regularly than usual while using the Products and that in the event the Products needed to be attempted to revise or be removed that the procedures to remove segments of the Products had a very high failure rate and/or needed to be performed repeatedly;

h. That Defendant Coloplast's Products were manufactured negligently;

i. That Defendant Coloplast's Products were manufactured defectively; and

j. That Defendant Coloplast's Products were designed negligently and designed defectively.

k. That Defendant Boston Scientific's Products were manufactured negligently;

l. That Defendant Boston Scientific's Products were manufactured defectively; and

m. That Defendant Boston Scientific's Products were designed negligently and designed defectively.

234. If the Defendants provided full and accurate warnings with the Products to the Plaintiff or her healthcare providers prior to the dates of implant, the Products would not have been implanted inside the Plaintiff. The inadequate warnings provided with the Products proximately caused the Plaintiff's injuries.

235. As a direct and proximate result of the Defendant Coloplast and Defendant Boston Scientific's failure to warn, Plaintiff has suffered serious and permanent injuries, including pain and suffering, loss of capacity for the enjoyment of life, pelvic and vaginal pain, complex extrusion and erosion of the mesh in her body, chronic inflammation with swollen inflamed tissue in her vagina, mesh adhesion to her vagina and surrounding tissue, tissue damage and death of her vaginal wall tissue and nerves, failure of the mesh to treat her underlying conditions, new onset, urinary and pelvic complications, mesh deformation including coiling, contracting and curling of the mesh insider her vagina, mesh hardening and stiffening, intervention for her pain including the need for painful surgical interventions to remove portions of all the Products, as well as the need for continuing and future medical care and treatment. She has incurred significant expenses for medical care and treatment and will continue to incur such expenses in the future.

STRICT LIABILITY – MANUFACTURING DEFECT AGAINST DEFENDANT COLOPLAST CORP., DEFENDANT COLOPLAST MANUFACTURING US, LLC., AND DEFENDANT BOSTON SCIENTIFIC CORP.

236. Plaintiff Smith repeats and realleges all allegations contained in this Complaint as if fully set forth in this Count.

237. The Restorelle XL, Direct Fix Anterior and Advantage Fit Products, as manufactured, did not perform as intended.

238. The Products were defective when they left the Defendant Coloplast and Defendant Boston Scientific's control as a result of a flaw in the manufacturing process, workmanship, and/or materials of which the product was made.

239. At all times relevant herein, the Defendants were engaged in the business of designing, developing, manufacturing, testing, packaging, promoting, marketing, distributing, labeling, and/or selling the Products.

240. At all times relevant herein, the Products were expected to reach, and did reach, consumers in the State of Texas and throughout the United States without substantial change in the condition in which they were sold.

241. The implantation of the Products into Plaintiff was reasonably foreseeable, and it was used in the manner for which they were known by the Defendants.

242. At all times relevant herein, the Products were designed, developed, manufactured, tested, packaged, promoted, marketed, distributed, labeled, and/or sold by Defendant Coloplast and Defendant Boston Scientific in a defective and unreasonably dangerous condition at the time it was placed in the stream of commerce in ways which include, but are not limited to, one or more of the following:

a. When placed in the stream of commerce, the Products contained manufacturing defects which rendered the Products unreasonably dangerous and subjected Plaintiff Smith to risks that exceeded the benefit of the Products, including but not limited to the risks of developing serious and dangerous side effects, serious infection, the need for additional procedures to remove and replace the Products, and/or the need for additional surgery as well as other severe and permanent health consequences;

b. The Products' manufacturing defects occurred while the Products were in the possession and control of the Defendants;

c. The Products were not made in accordance with Defendants specifications or performance standards; and the Products' manufacturing defects existed before it left the control of the Defendants.

243. As a direct and proximate result of the Defendant Coloplast's manufacturing defect, Plaintiff Smith has suffered serious and permanent injuries, including pain and suffering, loss of capacity for the enjoyment of life, pelvic and vaginal pain, complex extrusion and erosion of the mesh in her body, chronic inflammation with swollen inflamed tissue in her vagina, mesh adhesion to her vagina and surrounding tissue, tissue damage and death of her vaginal wall tissue and nerves, failure of the mesh to treat her underlying conditions, new onset, urinary and pelvic complications, mesh deformation including coiling, contracting and curling of the mesh insider her vagina, mesh hardening and stiffening, intervention for her pain including the need for painful surgical interventions to remove portions of both Products, as well as the need for continuing and future medical care and treatment. Plaintiff Smith has incurred significant expenses for medical care and treatment and will continue to incur such expenses in the future.

DISCOVERY RULE

244. Plaintiffs re-allege and incorporates by reference each of the foregoing paragraphs of this Complaint as if fully set forth herein and to the extent necessary would allege as follows:

245. Plaintiff could not have reasonably discovered the occasion, manner and/or means by which Defendant Coloplast or Defendant Boston Scientific's breach of duty occurred until within two years of the filing of this complaint. Further, Plaintiff did not and, exercising reasonable diligence, including consultation with medical professionals, could not discover the existence of her legal cause of action or the injuries caused by Defendant Coloplast and Defendant Boston Scientific's breach of duty and/or defective products until within two years of the filing of this complaint. Defendants continues to deny that its products are defective or cause injuries such as

those suffered by Plaintiff and Defendant continues to manufacture, market, and sell all or some of the products at issue.

246. Any applicable statute of limitations has been tolled by the knowing and active concealment and denial of material facts known by Defendant Coloplast and Defendant Boston Scientific when these Defendants had a duty to disclose and/or by the application of the discovery rule.

FRAUDULENT CONCEALMENT BY DEFENDANT COLOPLAST CORP. AND DEFENDANT COLOPLAST MANUFACTURING US, LLC., AND DEFENDANT BOSTON SCIENTIFIC

247. Plaintiff Smith incorporates by reference all preceding paragraphs as if fully set forth herein and further alleges as follows.

248. Defendants Coloplast and Defendant Boston Scientific falsely and fraudulently represented to the medical and healthcare community, Plaintiff Smith, her treating physician, and the public the safety of the Products implanted into Leah Smith.

249. The Defendants concealed that the design of the Restorelle XL, Direct Fix Anterior, and Advantage Fit devices lacked adequate safety data, that safety and efficacy of the Products had not been established, there were high complication rates associated with the Products, the Products did not offer permanent treatment, the stiff and rigid characteristic of the Products made it dangerous and increased the risks of injury in patients, the propensity for the pores of the Products to collapse made it dangerous and increased the risks of injury in patients, and the Products' design made them unreasonably susceptible to contracting, migrating, deformation, not holding in place, and eroding through vaginal tissue and organs.

250. Defendant Coloplast concealed from Dr. Shashoua that it removed the indication for use of implantation through the vagina of Restorelle XL's label.

251. Defendant Boston Scientific concealed from Dr. Shashoua and the public that the polypropylene used in the Advantage Fit products implanted into Leas Smith were not made from Marlex, but were made from counterfeit polypropylene purchased from China.

252. Defendant Coloplast and Defendant Boston Scientific concealed from Dr. Shashoua adverse events of patients Dr. Shashoua previously implanted with Defendants' pelvic mesh products.

253. Further, in representations to Plaintiff Smith and/or to Plaintiff Smith's healthcare providers, Defendant Coloplast and Defendant Boston Scientific fraudulently concealed and intentionally omitted the statements described herein and below which were material in nature:

a. That the Products were not as safe as other products, treatments and procedures available to treat pelvic organ prolapse or stress urinary incontinence;

b. That the risk of adverse events with the Products was higher than with other products, treatments and procedures available to treat pelvic organ prolapse and stress urinary incontinence;

c. The Products at issue here were not adequately tested;

d. That Defendant Coloplast and Defendant Boston Scientific deliberately failed to follow up on the adverse events from formal or informal reports from physicians and other healthcare providers and buried and/or misrepresented those findings;

e. That Defendant Coloplast and Defendant Boston Scientific were aware of the dangers of the Products in addition to and above and beyond those associated with other products, treatments and procedures available to treat pelvic organ prolapse and stress urinary incontinence;

f. That the Products were defective, and caused dangerous and adverse side effects, including but not limited to higher incidence of erosions, extrusions, adverse tissue response and rejection, contraction, migration, trauma, groin pain, vaginal pain, failure, and revision surgeries at a much more significant rate than other products, treatments and procedures available to treat pelvic organ prolapse or stress urinary incontinence;

g. That patients needed to be monitored more regularly than usual after implantation of the Products in the event the Products needed to be attempted to revise or be removed, that the procedures to remove segments of the product

were difficult/impossible to remove the mesh, had a very high failure rate, and/or removals may need to be performed repeatedly;

h. That the Products were manufactured negligently;

i. That the Products were manufactured defectively; and

j. That the Products were designed negligently and designed defectively.

254. Defendant Coloplast and Defendant Boston Scientific made claims and representations in its promotional materials to healthcare professionals and patients that the Products had innovative beneficial properties that increased the safety of the devices.

255. The representations made by the Defendants were, in fact, false and the omissions were misleading and fraudulent. The Defendants knew and/or had reason to know that those representations were false, and the omissions were misleading, and they willfully, wantonly, and recklessly disregarded the inaccuracies in the representations and the dangers and health risks to users of the Restorelle XL, Direct Fix Anterior, and Advantage Fit mesh devices, including Plaintiff Smith and her treating physician.

256. Defendant Coloplast and Defendant Boston Scientific's concealment and omissions of material facts concerning, inter alia, the safety of the Products were made purposefully, willfully, wantonly, and/or recklessly, to mislead Plaintiff Smith and Plaintiff Smith's physicians, hospitals and healthcare providers into reliance on the use of the Products, and to cause them to purchase, prescribe, dispense and/or use the Restorelle XL, Direct Fix Anterior, and Advantage Fit, as well as to cause Plaintiff to have the devices implanted in her body.

257. The information distributed to the public, the medical community, Plaintiff, and her treating physicians by Defendant Coloplast and Defendant Boston Scientific included, but was not limited to websites, information presented at medical and professional meetings, information disseminated by sales representatives to physicians and other medical care providers, reports, press

releases, advertising campaigns, television commercials, print advertisements, billboards and other commercial media containing material representations, which were false and misleading, and contained omissions and concealment of the truth about the dangers of the use of the Restorelle XL, Direct Fix Anterior, and Advantage Fit devices.

258. Defendants utilized direct-to-consumer advertising to market, promote, and advertise their Products.

259. Defendants had sole access to material facts concerning the defective nature of the their Products and their propensity to cause serious and dangerous side effects, and hence cause damage to persons who used the Products, including Plaintiff Smith in particular.

260. At the time these representations and omissions were made by Defendant Coloplast and/or Defendant Boston Scientific, and at the time Plaintiff Smith was implanted with the Products, Plaintiff Smith and her treating physician were unaware of the falsehood of these representations, misleading nature of omissions and statements, and reasonably believed them to be true. Plaintiff Smith did not discover the true facts about the dangers and serious health and/or safety risks, nor did Plaintiff discover the false representations of Defendant Coloplast, nor would Plaintiff with reasonable diligence have discovered the true facts or Defendants' misrepresentations.

261. Plaintiff Smith, as well as Plaintiff's physicians, hospitals and healthcare providers, reasonably relied on statements by the Defendants which negligently, fraudulently and/or purposefully did not include facts that were concealed and/or omitted that were critical to understanding the real dangers inherent in the use of the Products.

262. In reliance upon these false representations, Plaintiff Smith and her treating physician were induced to, and did use the Products, thereby causing Plaintiff Smith to sustain

severe personal injuries and damages. Defendant Coloplast and Defendant Boston Scientific knew or had reason to know that Plaintiff Smith and her treating physician and other healthcare providers had no way to determine the truth behind the Defendants' concealment and omissions, and that these included material omissions of facts surrounding the use of the Products as described in detail herein.

263. If Plaintiff Smith, her treating physician, or both would have been made aware of these purposefully suppressed and concealed facts, as set forth herein, Plaintiff Smith would not have used or consented to the implantation of the Products and her treating physician would have used the Products differently, warned about it differently or not used it at all.

264. Defendant Coloplast had a duty when disseminating information to the public to disseminate truthful information and a parallel duty not to deceive the public, Plaintiff Smith and Plaintiff Smith's healthcare providers.

265. Defendant Coloplast and Defendant Boston Scientific willfully, wantonly, recklessly and/or intentionally represented false, dangerous, and serious health and safety concerns inherent in the use of the Products to the public at large, for the purpose of influencing the sales of products known to be dangerous and defective, and/or not as safe as other alternatives.

266. Defendant Coloplast and Defendant Boston Scientific's intent and purpose in making these misrepresentations was to deceive and defraud the public, the medical community, Plaintiff Smith, and her treating physicians; to gain the confidence of the public, the medical community, Plaintiff Smith, and her treating physicians; to falsely assure them of the quality and fitness for use of the Products, and induce Plaintiff, and her treating physician, the public and the medical community to request, recommend, prescribe, dispense, and purchase the Products.

267. These representations, and others made by Defendant Coloplast and Defendant Boston Scientific, were false when made and/or were made with the pretense of actual knowledge when such knowledge did not actually exist and were made recklessly and without regard to the true facts.

268. Defendant Coloplast and Defendant Boston Scientific's wrongful conduct constitutes fraud and deceit and was committed and perpetrated willfully, wantonly, and/or purposefully on Plaintiff Smith.

269. Defendant Coloplast and Defendant Boston Scientific knew and had reason to know that their Products could and would cause severe and grievous personal injury to the patients implanted with the devices, and that the devices were inherently dangerous in a manner that exceeded any purported, inaccurate, or otherwise downplayed warnings.

270. As a direct and proximate result of the Defendant Coloplast and Defendant Boston Scientific's conduct, Plaintiff has suffered serious and permanent injuries, including pain and suffering, loss of capacity for the enjoyment of life, pelvic and vaginal pain, complex extrusion and erosion of the mesh in her body, chronic inflammation with swollen inflamed tissue in her vagina, mesh adhesion to her vagina and surrounding tissue, tissue damage and death of her vaginal wall tissue and nerves, failure of the mesh to treat her underlying conditions, new onset, urinary and pelvic complications, mesh deformation including coiling, contracting and curling of the mesh insider her vagina, mesh hardening and stiffening, intervention for her pain including the need for painful surgical intervention to remove segments of the eroded mesh, as well as the need for continuing and future medical care and treatment. She has incurred significant expenses for medical care and treatment and will continue to incur such expenses in the future.

LOSS OF CONSORTIUM

271. As a direct and proximate result of the above-described injuries sustained by Plaintiff Leah Smith, her spouse, Plaintiff Steven Smith, has suffered a loss of spousal consortium, companionship, society, affection, services, and support. These losses have been incurred and will continue to be incurred in the future.

DAMAGES

272. The injuries, conditions, and complications suffered by Plaintiff Leah Smith, as a result of being implanted with the Products include, but are not limited to, erosion, mesh contraction, mesh deformation infection, fistula, inflammation, scar tissue, organ perforation, dyspareunia (pain during sexual intercourse), blood loss, neuropathic and other acute and chronic nerve damage and pain, pelvic floor damage, chronic pelvic pain, multiple mesh revision surgeries, emotional distress and mental anguish, and other debilitating complications, including those listed above. In addition, Plaintiff Leah Smith will need to be continuously monitored as a result of being implanted with the Products. A monitoring procedure exists for individuals experiencing physical and mental injuries from mesh implanted in patients with pelvic organ prolapsed and/or stress urinary incontinence. The monitoring procedure has been prescribed by a qualified physician and is reasonably necessary according to contemporary scientific principles. As such, Plaintiff Leah Smith is entitled to future medical monitoring and treatment directly related to the existing injuries caused by the Products implanted by Dr. Shashoua.

273. In the future, based on a reasonable degree of medical probability, Plaintiff Leah Smith will endure significant mental and physical pain and suffering, permanent injury, further medical treatment and surgical procedures.

274. Further, as a direct and proximate result of the negligence of Defendant Coloplast and Defendant Boston Scientific, it was necessary for Plaintiff Leah Smith, to secure medical and

hospital services, including drugs and other medications, and it is reasonably probable that she may require medical, hospital, and drug services in the future beyond this date, all for which Plaintiff sues for a just and reasonable sum in excess of the minimal jurisdictional limits of the Court.

275. Plaintiff, Steven Smith, is the spouse of Plaintiff Leah Smith, and as a direct and proximate result of Defendants' conduct as described in this Complaint, Plaintiff Steven Smith has necessarily paid and has become liable to pay for medical aid, treatment, attendance and medications, and will necessarily incur further expenses of a similar nature in the future.

276. As a direct and proximate result of Defendants' conduct as described in this Complaint, Plaintiff Steven Smith suffered and, in the future, will suffer the loss of his wife's affection, companionship, services, society, and other damages.

277. As a direct and proximate result of Defendant's conduct as described in this Complaint, Plaintiff Steven Smith is entitled to and hereby seeks all such compensatory damages, punitive damages, attorney fees, reimbursement for all past, present and future health and medical care costs related to the Product, and any and all other damages allowed by law, in an amount to be determined at trial.

EXEMPLARY DAMAGES

278. Defendants' conduct described herein, when viewed objectively from the standpoint of Defendant at the time of the occurrence, involved an extreme degree of risk, considering the probability and magnitude of the potential harm to others. Moreover, Defendants had actual, subjective awareness of the risk involved, but nevertheless proceeded with conscious indifference to the rights, safety, and welfare of others. Thus, Plaintiff seeks exemplary damages in an amount to be determined by the jury.

PUNITIVE DAMAGES

279. Plaintiff Smith repeats and realleges all allegations contained in this Complaint as if fully set forth in this Count.

280. Defendant Coloplast sold the Restorelle XL and Direct Fix Anterior to Plaintiff's healthcare providers and other healthcare providers throughout the United States without doing adequate testing to ensure that the devices were reasonably safe for implantation in the female pelvic area.

281. Defendant Coloplast sold the Restorelle and Direct Fix Anterior to Plaintiff's health care providers and other health care providers throughout the United States in spite of its knowledge that the devices caused severe complications and injuries, including, but not limited to the injuries suffered by Plaintiff.

282. Defendant Boston Scientific sold the Advantage Fit to Plaintiff's healthcare providers and other healthcare providers throughout the United States without doing adequate testing to ensure that the devices were reasonably safe for implantation in the female pelvic area.

283. Defendant Boston Scientific sold the Advantage Fit to Plaintiff's health care providers and other health care providers throughout the United States in spite of its knowledge that the devices caused severe complications and injuries, including, but not limited to the injuries suffered by Plaintiff.

284. At all times material hereto, Defendant Coloplast and Defendant Boston Scientific misrepresented material safety facts about the safety of the device.

285. Defendant Coloplast and Defendant Boston Scientific's misrepresentations included knowingly withholding material information from the medical community and the public,

from Plaintiff Smith, and from her treating physician concerning the safety and efficacy of the device.

286. At all times material hereto, all Defendants knew and intentionally and/or recklessly disregarded the fact that the Products cause debilitating, irreversible and catastrophic side effects with greater frequency than safer alternative products and/or methods of treatment.

287. At all times material hereto, all Defendants intentionally misstated and misrepresented data so as to minimize the true and accurate risk of injuries and complications caused by the Products.

288. Notwithstanding the foregoing, Defendant Coloplast and Defendant Boston Scientific aggressively marketed their Products to consumers, including Plaintiff and her treating physician, without disclosing the true risk of side effects and complications and with fraudulent claims.

289. Defendant Coloplast knew Restorelle XL and Direct Fix Anterior were defective and unreasonably dangerous, but continued to manufacture, produce, assemble, market, distribute, and sell the devices so as to maximize sales and profits at the expense of the health and safety of the public, including Plaintiff, in conscious or reckless disregard of the foreseeable harm caused by the devices.

290. Defendant Boston Scientific knew the Advantage fit was defective and unreasonably dangerous, but continued to manufacture, produce, assemble, market, distribute, and sell the devices so as to maximize sales and profits at the expense of the health and safety of the public, including Plaintiff, in conscious or reckless disregard of the foreseeable harm caused by the devices.

291. Defendant Coloplast and Defendant Boston Scientific intentionally, recklessly or negligently failed to disclose information that deprived Plaintiff and the public of necessary information to enable them to weigh the true risks of using the device against the benefits. This failure constitutes willful or wanton behavior, or gross negligence.

292. As a direct and proximate result of the foregoing acts and omissions by Defendant Coloplast and Defendant Boston Scientific, Plaintiff Smith has required and will require health care and services, and has incurred medical, health care, incidental, and related expenses. Plaintiff Smith is informed and believe and further allege that Plaintiff Smith will in the future be required to obtain further medical care and/or hospital care and medical services.

293. Defendant Coloplast and Defendant Boston Scientific's conduct, as described herein, shows willful misconduct, malice, fraud, wantonness, oppression, or that entire want of care which raises the presumption of conscious indifference to consequences, thereby justifying an award of punitive damages in an amount determined by the jury and in accordance with the law.

DEMAND FOR JURY

294. Plaintiffs demand trial by jury of all issues herein and hereby tenders the appropriate fee.

PRAYER

Plaintiffs request Defendant be cited to appear and answer herein, and that upon final trial of this cause, Plaintiffs recover judgment against Defendant for Plaintiffs' damages, in both past and future, as set forth above including:

a. Physical pain and suffering;

b. Mental and emotional anguish and suffering;

c. Disfigurement and physical impairment;

d. Reasonable and necessary medical expenses; and

e. Post-judgment interest at the legal rate from the date of judgment;

f. Pre-judgment interest as allowed by law;

g. Costs of court;

h. Attorney's fees; and

i. Such other and further relief to which Plaintiff may be entitled.

Respectfully submitted,

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